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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE MERCK & CO., INC., SECURITIES, DERIVATIVE & "ERISA" LITIGATION	MDL No. 1658 (SRC) Case No. 2:05-CV-01151-SRC-CLW
THIS DOCUMENT RELATES TO: THE CONSOLIDATED SECURITIES ACTION	Case No. 2:05-CV-02367-SRC-CLW

CONSOLIDATED SIXTH AMENDED CLASS ACTION COMPLAINT

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Lead Plaintiffs and Court-appointed Class Representatives, the Public Employees' Retirement System of Mississippi, Steven LeVan, Jerome Haber and Richard Reynolds (collectively, "Lead Plaintiffs" or "Plaintiffs") bring this consolidated class action complaint for violation of the federal securities laws ("Complaint") against Merck & Co., Inc. from at least 1999 through 2004 ("Merck" or the "Company"), Dr. Alise Reicin (Merck Vice President, Project and Pipeline Leadership) and Dr. Edward Scolnick (Merck's former Executive Vice President for Science and Technology and President of Merck Research Laboratories) (the "Officer Defendants"). Merck and the Officer Defendants are referred to collectively herein as "Defendants."[1] The allegations against the Defendants are based on personal knowledge as to Plaintiffs' own acts and on information and belief as to all other matters, such information and belief having been informed by the investigation conducted by and under the supervision of their counsel ("Lead Counsel"), the materials referenced in this Complaint, and Lead Counsel's extensive consultations with pertinent experts. Plaintiffs believe that formal discovery, including document discovery and depositions of relevant witnesses, has provided and will continue to provide additional evidentiary support for their allegations. By and through their counsel, Plaintiffs, on behalf of themselves and the Class they represent, allege as follows:

I. PRELIMINARY STATEMENT

1. Plaintiffs bring this federal securities class action on behalf of themselves and a proposed class of persons and entities (the "Class") who purchased or acquired Merck securities between May 21, 1999 and September 29, 2004, inclusive (the "Class Period"). By Opinion and

[1] In accordance with the Court's prior Orders and decisions, Lead Plaintiffs do not assert claims: (i) against the dismissed Defendants; (ii) for the previously dismissed allegedly false and misleading statements during the Class Period; or (iii) for loss causation allegations concerning the November 1, 2004 *Wall Street Journal* article. However, Lead Plaintiffs reserve all rights with respect to these claims and Defendants.

Order dated January 30, 2013, the Court certified this action as a class action on behalf of all persons and entities who, from May 21, 1999 to September 29, 2004, inclusive, purchased or otherwise acquired Merck common stock or call options, or sold Merck put options.

2. Throughout the Class Period, Merck and the Officer Defendants made materially false and misleading statements of fact and belief concerning the safety profile and commercial viability of Merck's purported "blockbuster" drug VIOXX (a/k/a MK 966 or "rofecoxib"). As a result of Defendants' materially false and misleading statements, during the Class Period the value of Merck securities was significantly inflated. When the truth concerning VIOXX's safety and commercial viability finally began to emerge, the value of Merck securities fell sharply, causing Plaintiffs and Class members to suffer massive damages. In contrast, during the same period, Defendant Scolnick sold hundreds of thousands of shares of his own personal holdings of Merck stock, reaping lucrative insider selling profits in excess of ***$24.8 million***.

3. VIOXX is a non-steroidal anti-inflammatory drug ("NSAID") intended for use in the treatment of arthritis and other acute pain. Traditional NSAIDs, such as aspirin, ibuprofen and naproxen, function by inhibiting two enzymes: cyclooxygenase-1 ("COX-1"), which is associated with the maintenance of protective gastrointestinal ("GI") mucus, and cyclooxygenase-2 ("COX-2"), which is associated with the response to pain and inflammation. Unfortunately, the inhibition of COX-1 (and resulting inhibition of protective gastrointestinal mucus) by traditional NSAIDs can cause serious GI side effects. In developing VIOXX, Merck sought to develop a drug that would selectively suppress only COX-2 (thereby suppressing pain and inflammation) *without* suppressing COX-1 (thereby *avoiding* the adverse GI side effects associated with traditional NSAIDs).

4. There is an enormous worldwide market (estimated to be worth multiple billions of dollars *per year*) for a painkilling drug that lacks the adverse GI side effects of traditional NSAIDs, because patients suffering from diseases that cause chronic pain, such as arthritis, would be inclined to take such a drug on a daily basis. Consequently, Defendants and the market viewed VIOXX as a potential "blockbuster" drug.

5. The importance of VIOXX's commercial success to Merck could hardly be overstated, because at all relevant times Merck desperately needed to be able to market a major new drug whose revenue would be sufficient to off-set the more than $5 billion in annual revenue that Merck would be losing as *five* of Merck's existing drugs (Vasotec, Pepcid, Mevacor, Prilosec and Prinivil) were all scheduled to go "off patent" (*i.e.*, lose their patent protection) between August 2000 and the end of 2001. According to published reports, Merck's ability to survive as a separate company might even have been at risk if VIOXX failed to achieve and maintain blockbuster status.

6. Beginning with its press release of May 21, 1999 (the first day of the Class Period), in which Merck trumpeted the news that the FDA had approved VIOXX for the treatment of osteoarthritis, throughout the Class Period Defendants repeatedly touted VIOXX's safety profile, sales and commercial prospects in press releases, public statements, Merck-prepared medical journal articles, and filings with the SEC. Defendants repeatedly claimed, *inter alia*, that VIOXX was a "key growth driver" for Merck, that it had "robust" growth prospects for the treatment of arthritis and numerous other ailments, and that VIOXX sales would generate billions of dollars annually well into the future. By 2003, VIOXX was Merck's second best-selling drug (with annual sales of $2.5 billion), and Merck readily acknowledged that without VIOXX Merck "would be a very different company."

7. As set forth in detail below, however, Defendants' Class Period public statements concerning VIOXX were materially false or misleading, omitted to disclose numerous material facts necessary to make their statements not materially misleading, and/or misrepresented Merck's and its senior officers' and scientists' actual beliefs concerning VIOXX's safety and, consequently, its commercial prospects. Indeed, from the very start of the Class Period in May 1999, when Merck first announced the news of the FDA's approval of VIOXX, unbeknownst to the public, Merck internally had grave concerns that VIOXX caused serious cardiovascular ("CV") side effects, including myocardial infarction ("MI") (*i.e.,* heart attacks) and strokes. These serious concerns about VIOXX's CV risks were based on the research of one of Merck's own consultants (Dr. Garret FitzGerald) -- and the corroborating views privately provided to Merck by one of the Company's other prominent consultants (Dr. John Oates) -- which showed, based on urine analyses, that VIOXX upset one of the body's internal mechanisms by (a) suppressing prostacyclin (a chemical that occurs naturally in the body which *widens* blood vessels and *inhibits* blood clotting) while *simultaneously* (b) having *no* impact on the body's production of thromboxane (a chemical that *narrows* blood vessels and potently *promotes* blood clots).

8. Accordingly, as confirmed in internal Merck emails from the late 1990's that were only disclosed after the Class Period, as a result of Merck's "great concern" that VIOXX increases the risk of adverse CV events -- and that any clinical findings to that effect would "kill [the] drug" -- Merck scientists discussed how to design Merck's major clinical trials of VIOXX to minimize the risk that they would call attention to the extent of VIOXX's adverse CV (or "prothrombotic") side effects. Nonetheless, by no later than February 1998 Merck was in possession of a non-public internal analysis indicating that patients in its VIOXX clinical trials

had significantly higher rates of serious adverse CV events compared to patients taking placebo, including a statistically significant ***216%*** increased risk for adverse CV events among women taking VIOXX.

9. Although the FDA approved VIOXX in May 1999, Merck and the Officer Defendants knew that (a) the FDA would not allow it to market VIOXX with a label stating that VIOXX posed a significantly lower risk of adverse GI side effects than traditional NSAIDs unless and until Merck conducted a large scale gastrointestinal trial demonstrating that this was true, and (b) VIOXX's commercial prospects would be sharply curtailed if Merck failed to obtain an FDA-approved label affirming VIOXX's favorable GI safety. Accordingly, even though Merck had put off conducting a large-scale GI trial in 1997 (primarily due to its fears that such a trial would highlight VIOXX's prothrombotic side effects), in January 1999 -- by which time Merck was reasonably confident that it would obtain initial FDA approval of VIOXX -- Merck commenced a large scale VIOXX Gastrointestinal Outcomes Research ("VIGOR") trial. The VIGOR trial compared the results of a large patient group taking VIOXX to a similarly large patient group taking naproxen (a traditional NSAID marketed in the U.S. under the brand names Aleve and Naprosyn).

10. Merck designed the VIGOR study to minimize the likelihood that the results would show that VIOXX was prothrombotic, but the results of the VIGOR study nonetheless showed that patients taking VIOXX had a statistically significant higher incidence of adverse CV events (particularly heart attacks) than patients taking naproxen. Reviewing these results, Merck and the Officer Defendants concluded that VIOXX was prothrombotic, as they had feared. As defendant Edward Scolnick, Merck's Executive Vice President for Science and Technology and Merck's chief research scientist, acknowledged in a March 9, 2000 internal email to three other

senior Merck scientists (including Merck's Executive Director of Clinical Research, defendant Alise Reicin):

> I just received and went through the [VIGOR] data…. ***The [adverse] CV [cardiovascular] events are clearly there…. It is a shame*** but it is a low incidence ***and it is mechanism based as we worried it was***. [Dr. John] Oates and [senior Merck scientists] Alan [Nies] and Barry [Gertz] were right about the metabolite meanings ie urine Pg [prostaglandin] data….[1]

Defendant Scolnick's reference to the cause of the cardiovascular events being "mechanism based as we worried it was," and his statement that Drs. Oates, Nies and Gertz "were right" about the meaning of the "urine Pg [prostaglandin] data," was an admission that he understood that it was VIOXX's inhibition of prostacyclin (which was anti-thrombotic), combined with VIOXX's lack of any effect on thromboxane (which was *pro*-thrombotic), that caused patients taking VIOXX to experience a significantly increased risk of serious adverse CV events.

11. On March 27, 2000, Merck issued a press release discussing VIGOR's results. The release emphasized that VIGOR's results showed that VIOXX had a superior GI safety profile to naproxen, while also noting the significantly higher incidence of adverse CV events among VIOXX users compared to naproxen users. However, rather than acknowledge their conclusion that the statistically significant difference in the number of heart attacks and other adverse CV events in the VIGOR trial was "mechanism based" (*i.e.*, attributable to the manner in which VIOXX upset the body's homeostatic balance of prostacyclin and thromboxane) -- an admission that the Officer Defendants knew would likely "kill the drug" and precipitate a financial crisis for Merck -- the Officer Defendants tried to explain away the difference in VIGOR's adverse CV data by manufacturing a hypothesis that attributed VIGOR's CV results to

[1] Unless otherwise stated, all emphases herein are added.

the alleged "cardioprotective" properties of naproxen (the "naproxen hypothesis"). For example, as Merck's March 27, 2000 press release represented:

> ***[S]ignificantly fewer thromboembolic events were observed in patients taking naproxen in this GI outcomes study, which is consistent with naproxen's ability to block platelet aggregation.*** This effect on these events had not been observed previously in any clinical studies for naproxen. ***VIOXX, like all COX-2 selective medicines, does not block platelet aggregation and therefore would not be expected to have similar effects.***

To further support their "naproxen hypothesis," the press release further falsely represented that "[a]n extensive review of safety data from all other completed and ongoing clinical trials, as well as the post-marketing experience with VIOXX, showed no indication of a difference in the incidence of thromboembolic events between VIOXX, placebo and comparator NSAIDs."

12. The VIGOR results were widely reported. Market analysts understood that the higher rate of adverse CV events among VIOXX users in VIGOR could be due to either (a) purported cardioprotective properties of naproxen or (b) the prothrombotic effect of VIOXX. However, in the wake of Merck's repeatedly stated belief that the difference in the rate of adverse CV events between VIOXX and naproxen was likely due to and "consistent with" a cardioprotective effect of naproxen rather than a prothrombotic effect of VIOXX -- and in the wake of Merck's further assurances that there was no indication of a difference in the incidence of thromboembolic events between VIOXX, placebo and comparator NSAIDS in Merck's other clinical trial data -- virtually all members of the scientific, medical and Wall Street analyst communities either accepted or treated as plausible Merck's publicly stated view that the "naproxen hypothesis" was the "likeliest interpretation" of the VIGOR study results.

13. However, as defendant Scolnick's internal March 9, 2000 email confirms, unbeknownst to investors Merck actually believed that the increased CV events in VIGOR ***were***

caused by VIOXX, and as detailed below Merck concocted and advanced the "naproxen hypothesis" to protect VIOXX's commercial viability.

14. Over the weeks, months and years following the release of the VIGOR study results, Merck and the Officer Defendants continued to promote the "naproxen hypothesis" and to tout VIOXX's purported safety and blockbuster commercial viability, even as additional evidence continued to mount internally at Merck that VIOXX caused heart attacks and other serious adverse CV events.

15. For example, by no later than early April 2000 -- just a week after Merck first announced the results of the VIGOR study -- the preliminary results of another Merck study (the ADVANTAGE study, which also compared VIOXX to naproxen) became available internally at Merck. In an email to defendant Scolnick, defendant Reicin noted that there were ***seven*** heart attacks in one treatment group compared to only ***one*** in the other group. Although the two groups were still "blinded" at that time, there was little doubt that the former group was the VIOXX group and the latter group was the naproxen group. Moreover, as shown by internal Merck emails produced after the Class Period, in November 2000 defendant Reicin pressured another Merck scientist to change the reported cause of death of at least one of the patients in the ADVANTAGE trial who was taking VIOXX from "heart attack" to "unknown cause of death" so as not to "raise concerns" about VIOXX's CV safety and the validity of Merck's "naproxen hypothesis." Merck's manipulation of the ADVANTAGE data in this fashion was not publicly disclosed until April 2005, after the Class Period.

16. By April 2001, Merck and the Officer Defendants were also in possession of non-public information concerning the results of two clinical trials (known as Protocol 078 and Protocol 091) that they had conducted to assess the effects of VIOXX on Alzheimer's disease.

On both a standard "intention to treat" basis as well as a standard "on treatment" basis, these studies showed statistically significant increases in deaths (including a statistically significant increase in heart disease deaths) in patients being treated with VIOXX compared to those being treated with placebo -- results that obviously would have been material to investors and medical professionals alike.

17. However, Merck chose not to disclose to the public that its internally prepared analyses showed a statistically significant increase in mortality (including a statistically significant increase in heart disease deaths) for VIOXX patients whether using standard "intention-to-treat" or "on treatment" analysis. Instead, Merck attempted to conceal these studies' statistically significant results by creating and then employing a non-standard "On Drug" methodology pursuant to which it reported substantially reduced -- and ***not*** statistically significant -- increased mortality risks for patients who used VIOXX in these two trials. Merck's concealment of the true nature and extent of the safety risks of VIOXX from the institutional review boards ("IRB's") that were responsible for patient enrollment at the clinical test sites for these trials was sufficiently improper and outrageous that, when the relevant facts were finally disclosed in 2008, the authors of an article published in the *Journal of the American Medical Association ("JAMA")* characterized Merck's extraordinary misconduct as "violating the trust of [the] human participants who volunteered to participate" in the trials.

18. Notwithstanding this growing body of additional, material non-public information in Merck's possession concerning VIOXX's association with increased CV risks and deaths, Merck continued to falsely downplay any concerns about VIOXX's safety or profit potential, and to falsely reaffirm its purported belief in the "naproxen hypothesis." For example, on August 21, 2001 -- the day before *JAMA* published an article that expressed concerns about VIOXX's

possible prothrombotic effects -- a Merck spokesman assured *Bloomberg News* that Merck had "additional data beyond what [the authors of the *JAMA* article] cite, and the findings are very, very reassuring. VIOXX does not result in any increase in cardiovascular events compared to placebo." Approximately six weeks later, on October 9, 2001, *The New York Times* quoted defendant Scolnick reiterating (a) that Merck's belief that the "naproxen hypothesis" remained the "likeliest interpretation" of the VIGOR data, and (b) that Merck had found no evidence in other studies that VIOXX increased the risk of heart attacks. Scolnick added that without the "theoretical question" raised by Dr. FitzGerald's early research concerning VIOXX's impact on prostacyclin "no one would have a question remaining in their mind that there might be an additional interpretation" (*i.e.*, that VIOXX caused increased CV risks). Similarly, in an April 2002 conference call, a Merck spokesman reiterated the Company's "belief that the effects seen in VIGOR were [due to] the anti-platelet effect of naproxen" and that that was "a position that Merck has always had."

19. In the fall of 2003, the results of a Merck-funded study at Brigham and Women's Hospital in Boston (the "Brigham Study") became public. The Brigham Study, which looked at the records of almost 55,000 Medicare patients over the age of 65, found an increased risk of heart attack in patients taking VIOXX, compared with patients taking Celebrex (a rival COX-2 inhibitor that was VIOXX's main competitor) and with patients not taking any painkiller. The results of the Brigham Study raised doubts about Merck's "naproxen hypothesis," but Merck aggressively countered the results of the study by arguing that epidemiological studies (such as the Brigham study) were not as significant as the results of clinical trials, and by vigorously reiterating its purported belief in the "naproxen hypothesis." As a result of Merck's renewed public defense of its "naproxen hypothesis," investor concerns about VIOXX were substantially

assuaged, and the market continued to be materially misled as to Merck's actual beliefs and the true extent to which VIOXX's commercial viability was in jeopardy.

20. On September 30, 2004, Merck announced that it was withdrawing VIOXX from the market based on a new study showing an "increased risk of confirmed cardiovascular events beginning after 18 months of continuous therapy." In response to this news, the price of Merck common stock plummeted more than $12 in heavy trading to close at $33.00, down approximately 27% from its closing price the previous day. Securities analysts expressed shock and surprise at the sudden withdrawal of VIOXX.

21. Since the end of the Class Period in September 2004, and as noted above and as further described below, significant information that was previously unknown to and/or concealed from Plaintiffs and investors has been obtained by Lead Counsel which details Merck's and the Officer Defendants' knowing concealment and manipulation of VIOXX trial data, their lack of good faith belief in the Company's "naproxen hypothesis," their efforts to intimidate and discredit anyone who attempted to seriously challenge VIOXX's safety, and their knowingly (or at least recklessly) materially false and misleading public assurances throughout the Class Period that there was "no indication" that VIOXX caused adverse CV events, and that VIOXX would continue to generate billions of dollars in annual sales for Merck for years to come. By this Complaint, Plaintiffs, on behalf of themselves and the other members of the Class, seek a recovery for the massive financial losses that they and their fellow Class members have suffered as a result of Defendants' violations of the federal securities laws, as further set forth herein.

II. THE CLAIMS ASSERTED IN THIS COMPLAINT

22. This Complaint sets forth claims under Sections 10(b), 20(a) and 20A of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §§ 78j(b), 78t(a), and 78t-1,

and the rules and regulations promulgated thereunder, including SEC Rule 10b-5, 17 C.F.R. § 240.10b-5 ("Rule 10b-5"), against the Defendants, who were knowing or reckless participants in defrauding investors in connection with their material misrepresentations and omissions concerning VIOXX.

III. JURISDICTION AND VENUE

23. This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa. In addition, because this is a civil action arising under the laws of the United States, this Court has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1337.

24. Venue is proper in this District pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa. Defendant Merck at all relevant times was, and still is, headquartered in this District and many of the acts and transactions that constitute the violations of law complained of herein, including the dissemination to the public of materially false and misleading statements, occurred in and/or issued from this District. In addition, venue is proper in this District pursuant to the Order of the Judicial Panel on Multidistrict Litigation, dated February 23, 2005.

25. In connection with the acts alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the U.S. mails, interstate telephone communications and the facilities of national securities exchanges.

IV. PARTIES

A. The Plaintiffs

26. Court-appointed and certified Co-Lead Plaintiff, the Public Employees' Retirement System of Mississippi ("Mississippi PERS") is a pension fund established for the benefit of the current and retired public employees of the State of Mississippi. Mississippi PERS

is responsible for the retirement income of employees of the State, including current and retired employees of the state's public school districts, municipalities, counties, community colleges, state universities, libraries and water districts. Mississippi PERS provides benefits to over 60,000 retirees, and is responsible for providing retirement benefits to more than 250,000 current public employees. Mississippi PERS purchased shares of common stock of Merck during the Class Period and suffered damages as a result of the violations of the federal securities laws alleged herein.

27. Court-appointed and certified Co-Lead Plaintiffs Steven LeVan, Jerome Haber and Richard Reynolds purchased shares of common stock of Merck during the Class Period and suffered damages as a result of the violations of the federal securities laws alleged herein. Co-Lead Plaintiffs Mississippi PERS, LeVan, Haber and Reynolds previously submitted certifications reflecting their transactions in Merck common stock during the Class Period, which are incorporated by reference herein.

B. The Defendants

1. Merck

28. Defendant Merck is a global pharmaceutical company that develops, manufactures, and markets a broad range of human and animal health products. As of September 29, 2004, the Company had in excess of 2.2 billion shares of common stock outstanding, which were actively and efficiently traded on the New York Stock Exchange (the "NYSE"). Merck is a New Jersey corporation with its principal place of business located at One Merck Drive, Whitehouse Station, New Jersey.

2. The Officer Defendants

29. (a) Defendant Edward Scolnick ("Scolnick") was Merck's Executive Vice President for Science and Technology and President of Merck Research Laboratories from the

beginning of the Class Period through and including December 31, 2002, when he stepped down. From January 1, 2003 through the end of the Class Period, Scolnick served as President *Emeritus*, Merck Research Laboratories. During 1999, 2000, and 2001, Scolnick was also a member of the Company's Management Committee. As the senior Merck officer in charge of Merck's research and development, Scolnick was intimately involved in and fully conversant with the development, research, and testing of VIOXX, and was well aware of the risks and problems associated with the drug.

(b) As detailed herein, during the Class Period, defendant Scolnick was one of Merck's chief spokespersons in connection with information provided to the public about VIOXX, and he made public statements concerning VIOXX and Merck's financial condition, performance, and prospects that were materially false and misleading and omitted to state material facts, including materially false and misleading statements in documents filed with the SEC during the Class Period.

(c) As detailed herein, defendant Scolnick was a direct, substantial, and primary participant in the wrongdoing alleged herein. While in possession of materially adverse non-public information regarding Merck, Scolnick personally profited from the sale of his personal holdings of Merck securities at artificially inflated prices during the Class Period. During the Class Period, Scolnick sold at least 381,200 shares of his personal holdings of Merck stock, recognizing more than $24.8 million in insider selling profits. In addition, from the beginning of the Class Period through his retirement, Scolnick received substantial performance-based bonuses and other compensation based on, among other things, growth in Merck's earnings per share, Merck's sales compared to certain of Merck's competitors and the change in the Company's return on operating assets versus the prior year. From January 1, 2003 through

the end of the Class Period, Scolnick was no longer subject to public reporting requirements concerning the sale of Merck stock. Without the benefit of further discovery, Plaintiffs are unable to ascertain whether Scolnick sold any additional shares of his personal holdings of Merck common stock during the Class Period.

30. (a) Defendant Alise S. Reicin ("Reicin") was, at all relevant times, the Executive Director of Clinical Research at Merck Research Laboratories. Reicin was responsible for overseeing research with regard to the safety and efficacy of Merck products, including VIOXX, and supervised the VIGOR Study.

(b) As detailed herein, defendant Reicin was a direct, substantial, and primary participant in the wrongdoing. As detailed herein, during the Class Period, Reicin made public statements concerning VIOXX that were materially false and misleading and omitted to state material facts.

(c) As defendant Reicin was not required to file information with the SEC concerning her transactions in Merck securities during the Class Period, without the benefit of further discovery Plaintiffs are unable to determine whether Reicin, while in possession of material adverse information regarding Merck, profited from the sale of Merck securities at artificially inflated prices.

V. CLASS ACTION ALLEGATIONS

31. Plaintiffs bring this action as a class action, pursuant to Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure, on behalf of a Class consisting of all persons and entities who purchased or acquired the securities of Merck during the period from May 21, 1999 through September 29, 2004, inclusive. Excluded from the Class are Defendants; Merck's affiliates and subsidiaries; the officers and directors of Merck and its subsidiaries and affiliates at all relevant times; members of the immediate family of any excluded person; the legal representatives, heirs,

successors, and assigns of any excluded person or entity; and any entity in which any excluded person or entity has or had a controlling interest.

32. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Merck had billions of shares of common stock outstanding, which were actively traded on the NYSE. The average daily trading volume during the Class Period was more than 6.5 million shares. Although the exact number of Class members is unknown to Plaintiffs at this time, Plaintiffs believe that there are at least thousands of members of the proposed Class. Members of the Class can be identified from records maintained by Merck or its transfer agent, and can be notified of the pendency of this action by mail and publication using forms of notice similar to those customarily used in securities class actions.

33. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class were similarly damaged by Defendants' conduct as complained of herein.

34. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation. Plaintiffs have no interests that conflict with the interests of the Class.

35. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether Defendants' statements and omissions during the Class Period materially misrepresented the safety and commercial viability of VIOXX;

(b) whether Defendants' acts and omissions as alleged herein violated the federal securities laws;

(c) whether the Officer Defendants are personally liable for the alleged misrepresentations and omissions described herein;

(d) whether Defendants' misrepresentations and omissions caused the Class members to suffer a compensable loss; and

(e) whether the members of the Class have sustained damages, and the proper measure of damages.

36. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy. Because the damages suffered by many individual Class members will be small relative to the expense and burden of individual litigation, it is practically impossible for most members of the Class to redress individually the wrongs done to them. There will be no difficulty in the management of this action as a class action.

VI. THE DEFENDANTS' FRAUD

37. As discussed below, each of the Defendants is liable as a participant in a fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of Merck securities by disseminating materially false and misleading statements (including statements of opinion or belief) and/or concealing material adverse facts regarding VIOXX. The scheme: (i) deceived the investing public regarding the commercial viability of VIOXX and the intrinsic value of Merck securities; (ii) enabled Merck and the Officer Defendants to artificially inflate the price of Merck securities; (iii) enabled defendant Scolnick to sell over ***$32.4 million*** of his personal holdings of Merck shares; and (iv) caused Plaintiffs and other members of the Class to suffer damages as a result of the Defendants' misconduct.

A. Merck Develops VIOXX in an Attempt to Create a Blockbuster "Selective" NSAID with Reduced Gastrointestinal Side Effects

1. The Problems Associated With Traditional, Non-Selective NSAIDs

38. Traditional NSAIDs reduce inflammation and pain, and are widely used to treat persons suffering from arthritis and muscle pain, and other inflammatory conditions. NSAIDs work by inhibiting the cyclooxygenase ("COX") enzyme, which catalyzes the formation of two

prostaglandins in the body -- prostacyclin and thromboxane -- which play a central role in inflammation. Prostacyclin is a chemical that occurs naturally in the body that *widens* blood vessels and *inhibits* blood clotting. Thromboxane is a chemical that *narrows* blood vessels and potently *promotes* blood clotting. These two chemicals, which have opposite effects, exist in the body in a natural balance referred to as "homeostasis."

39. Long-term use of traditional NSAIDs -- such as aspirin, ibuprofen and naproxen -- can cause gastrointestinal ("GI") and renal (kidney) problems. Adverse GI effects caused by traditional NSAIDs include nausea, indigestion, and, in more severe cases, gastric perforation, ulceration and bleeding. Adverse renal effects include salt and fluid retention, and high blood pressure. The risk of developing such problems increases with dosage and the duration of treatment.

2. Discovery of the COX-2 Enzyme Raises Hopes that a Selective NSAID Could be Developed Which Would Not Cause the Gastrointestinal Problems Associated with Traditional NSAIDs

40. For many years, scientists only recognized one form of the COX enzyme. This form, now known as COX-1, is naturally present in the stomach lining, where it helps play a protective role in preventing erosion of the stomach lining by the stomach's own acid.

41. In the early 1990s, scientists discovered a second form of the COX enzyme, referred to as COX-2. COX-2 is not normally present in the stomach and only appears in the stomach when there is inflammation, and at the site of the inflammation. Following the discovery of COX-2, scientists concluded that COX-2, but not COX-1, was primarily involved with inflammation.

42. Traditional NSAIDs inhibit both COX-1 and COX-2. In the wake of the discovery of COX-2, scientists realized that traditional NSAIDs relieved pain and inflammation by inhibiting COX-2, but caused GI problems by inhibiting COX-1. This new-found knowledge

raised hopes that a drug could be developed that would inhibit COX-2 but not COX-1, and thereby provide the relief from pain and inflammation provided by traditional NSAIDs while simultaneously avoiding the GI problems associated with traditional NSAIDs.

3. Merck Races to Develop and Stay Ahead of Its Competitors in Developing a COX-2 Inhibitor

43. Shortly after the discovery of COX-2, Merck began work on trying to develop a novel NSAID that would inhibit COX-2 without inhibiting COX-1.

44. Merck, like other pharmaceutical companies and Wall Street analysts, recognized that such a pill would have the potential for enormous commercial success because patients suffering from diseases that cause chronic pain and inflammation, such as arthritis, would be inclined to take a painkiller that lacked the adverse GI side effects of traditional NSAIDs on a daily basis. Merck also recognized that the first company to bring such a pill to market would have a tremendous competitive advantage. For example, in a 1996 internal Product Development Plan for VIOXX, Merck projected that ***"the base case valuation for MK-966 [VIOXX] is expected to be $889MM assuming the product is first to market. In a second to market scenario, the valuation falls to $278MM, implying a significant value ($611MM) to being first to market."***

45. Merck scientists and executives, however, "feared they were in a race -- and running second" from the get-go, as reported in a January 10, 2001 *Wall Street Journal* article entitled "The Cure: With Big Drugs Dying, Merck Didn't Merge -- It Found New Ones" (the "January 2001 *Wall Street Journal* article"). As the article reported, in 1994 defendant Scolnick, the President of Merck Research Laboratories, "ordered researchers in [Merck's lab in] Montreal to pursue [this] work as fast as they could." Underscoring this urgency, the article quoted Scolnick as stating that he would call the Montreal lab "every other day and say, 'Hey, is

everybody working on this project?'" Scolnick added that "they got the message that it was important."

46. Defendant Scolnick and others at Merck recognized that G.D. Searle, a division of Monsanto Company, was their primary competition. According to the January 2001 *Wall Street Journal* article, Scolnick and Merck were aware of rumors that Dr. Philip Needleman, a renowned pharmacologist at Washington University in St. Louis who had written articles on the creation of a COX-2 inhibitor, had "subsequently crossed town to join Monsanto Co. [and] was working on a similar drug for that company."

47. By October 1994, Merck had developed two compounds that performed well in test-tube testing. According to the January 2001 *Wall Street Journal* article, "Normally, Dr. Scolnick would have chosen one of these to put through the expensive and risky process of testing in humans. ***But the project was so important – and Merck appeared to be in such a high-stakes competition with Monsanto – that he decided to put both compounds in clinical trials***."

48. Only one of Merck's two compounds was found to inhibit COX-2 effectively. In 1995, Merck gave the successful compound the code name MK-966 (also known as "rofecoxib" and later marketed under the trade name "VIOXX") and began running it through further clinical trials. At about the same time, Monsanto/Searle selected a different compound, SC-58635 (also known as "celecoxib" and later marketed under the trade name "Celebrex"), as its lead compound in its efforts to develop a COX-2 inhibitor, and began running Celebrex through similar clinical trials.

49. In Merck's 1996 internal Product Development Plan, Merck recognized that:

> ***Searle is seen as major competition in the area of highly selective COX-2 inhibitors.*** They have reported their targeted filing date for

> OA [osteoarthritis] as 4Q98. ***If they were to be the first entry in the market with the new class of compounds it would have a significant negative impact on our financial projections.*** To reduce the risk of MK-966 [VIOXX] as the second entry, an accelerated development strategy is proposed and the additional resources needed to achieve the stated objectives are being requested. Phase III will be initiated almost in parallel with Phase IIB and a GI outcomes study will be initiated prior to completion of Phase III. This strategy with its own attendant risks (see below)[2] is necessitated by the commercial implications of not being the first entry.

50. In order to achieve its marketing objectives, Merck needed to show not only that VIOXX was effective as a treatment for pain from arthritis and other ailments, but also that VIOXX was less likely to cause GI problems than traditional NSAIDs. Before the FDA would allow Merck to make that claim, Merck needed to conduct a large-scale gastrointestinal outcomes trial. Absent such a trial, the FDA would require the label for VIOXX (or any other COX-2 inhibitor) to carry the same GI warning that it required for all traditional NSAIDs. (As discussed below, however, Merck found it expedient to defer performing such a GI outcomes trial until *after* it was reasonably assured that VIOXX would receive initial FDA approval.)

51. In February 1998, Pfizer Inc., one of the world's largest pharmaceutical companies and a major competitor of Merck, reached an agreement with Monsanto/Searle to co-promote and develop Celebrex as well as a "next generation" COX-2 inhibitor. On February 23,

[2] The risks identified "below" included (1) whether Merck's proposed clinical trials would be sufficient to obtain FDA approval for a drug label which would state that VIOXX had a lower incidence of significant GI complications than chosen comparator NSAIDs; (2) whether Merck would choose the right dosage of VIOXX for Phase III testing, recognizing that Phase III would "be initiated prior to completion of the Phase IIB dose finding study"; (3) whether Merck could secure an adequate supply of naproxen for its large scale gastrointestinal outcomes trial; (4) whether certain endoscopy studies Merck was planning to perform would be acceptable to the FDA; (5) whether the FDA would approve a proposed study comparing VIOXX with nabumetone; (6) whether the timeline for the large scale GI outcomes trial scheduled to begin in the third quarter of 1997 could be maintained; and (7) whether the FDA would accept one year patient exposure data from the large-scale GI outcomes trial with two year data to follow in a Safety Update Report.

1998, David Anstice, Merck's President of Human Health -- The Americas, sent a memo to his staff with the subject header "VIOXX," stating:

> ***Battle is now joined with Pfizer in another major therapeutic area and one which is CRITICAL to Merck from 2000 onwards.*** We should assume Pfizer will promote [Celebrex] everywhere. ***We simply CANNOT LOSE in any single market in The Americas.*** We need to have superior marketing positioning and plans, and better execution. We need to have opinion leaders with us, and we need to identify the correct resource needs. Every Sales VP, every Sales BD, BM and Rep must personally accept the challenge of winning versus Searle/Pfizer, that is greater than 50% share of the COX-II Inhibitor market. Let's start thinking this way from today.[3]

52. To Merck's dismay, Monsanto/Searle completed its clinical trials first. On June 29, 1998, Monsanto/Searle and Pfizer submitted a New Drug Application ("NDA") to the FDA for Celebrex. Merck would not submit its NDA for VIOXX to the FDA until November 23, 1998 -- almost five months later.

53. On December 31, 1998, Merck received further bad news when the FDA gave Pfizer and Monsanto/Searle approval to begin marketing Celebrex (albeit with the standard GI warning). Pfizer and Monsanto/Searle launched Celebrex in February 1999 with massive marketing campaigns directed at both physicians and consumers. Celebrex "quickly became the most successful drug launch in U.S. history" according to the January 2001 *Wall Street Journal* article.

54. Several industry analysts predicted that Celebrex's successful launch would make it difficult for VIOXX to succeed. As reported in an April 14, 1999 *Wall Street Journal* article entitled "Merck's Health Hinges on Sales Of Arthritis Pill" (the "April 1999 *Wall Street Journal* article"), certain analysts held the view that "Celebrex ha[d] taken off so fast with arthritis

[3] Upper case letters and underlining contained in original.

sufferers that there are comparatively few dissatisfied patients left for VIOXX to tap and thus it could be difficult for Merck to persuade recent Celebrex converts to switch to VIOXX."

4. Merck's Huge Financial Stake in the Success of VIOXX

55. The April 1999 *Wall Street Journal* article bluntly described Merck's dependence on the success of VIOXX: "***Merck needs VIOXX to be a winner. After years of rapid sales and profit growth, patents on some of its biggest sellers will soon expire, opening the door to less-expensive generic versions. The company is also grappling with a slowdown in sales growth of its big cholesterol-drug franchise and was recently hit with a delay in developing a new antidepressant.***"

56. The January 2001 *Wall Street Journal* article further detailed Merck's patent expiration problem, stating: "Merck's problem, which at times has infected almost every big pharmaceuticals company, was that patents on several of its best-selling drugs would be expiring. Generic knock-offs would then eat deeply into market share and profits on drugs like Vasotec and Prinivil for hypertension, Mevacor for high cholesterol and Pepcid and Prilosec for ulcers."

57. More specifically, patents for these five drugs, which together accounted for a staggering ***$5.875 billion*** (or approximately 18%) of Merck's world-wide sales in 1999, were set to expire in 2000 and 2001:

Drug	1999 Worldwide Sales	Patent Expiration
Vasotec	$2.3 Billion	August 2000
Pepcid	$910 Million	October 2000
Mevacor	$600 Million	June 2001
Prilosec	$1.25 Billion	October 2001

Prinivil	$815 Million	December 2001

58. The January 2001 *Wall Street Journal* article also noted that "[e]ver since investors caught on to [Merck's impending patent expiration problem], Wall Street ha[d] been insisting that Merck join the merger rush sweeping the pharmaceuticals industry." According to the article, ***defendant Scolnick had recognized this coming "crisis" for fifteen years and "secretly feared that Merck might not survive it as an independent company."***

5. Merck's Successful VIOXX Product Launch in 1999

59. On May 20, 1999, the FDA gave Merck approval to market VIOXX. Desperate to catch up with Pfizer/Searle, Merck immediately set in motion an elaborate plan to get VIOXX onto the market and into the medicine cabinets of millions of Americans. Within eleven days of approval, VIOXX was stocked in 40,000 pharmacies, a feat that the January 2001 *Wall Street Journal* article called "remarkable."

60. Merck had also "girded for a marketing battle," having "hired 700 new sales representatives to push VIOXX and other new drugs," according to the April 1999 *Wall Street Journal* article.

61. On May 21, 1999, a *Dow Jones Newswire* report elaborated on the importance of VIOXX to Merck, and the anticipated competition between VIOXX and Celebrex: "The battle for this summer's blockbuster may not occur in movie theaters, but instead in the corner drugstore." The report quoted David Saks, a pharmaceutical analyst at Gruntal & Co.: ***"VIOXX to Merck is like the hot movie 'Star Wars' to the movie industry. . . . It's the biggest product for Merck."*** That day, Merck common stock closed at $69.20 -- up $2.47 from the previous day's closing price -- on heavy trading volume of 7,578,900, which was 53% greater than the previous day's trading volume.

62. Despite Merck's all-out efforts, an early report on CNBC-TV suggested VIOXX's sales were disappointing. A week after Merck launched VIOXX, CNBC reported that "Merck's Vioxx is not off to nearly as fast a start over its first seven days officially on the market as its main competitor in the same class, Celebrex." Upon receipt of this report, defendant Scolnick urgently emailed Jan Weiner, Merck's executive director of public affairs, at 1:43 a.m. on June 4, 1999, stating "Before I have a heart attack, please tell me what is really happening." After receiving reassurances from Weiner that the CNBC report was based on erroneous data, Scolnick thanked her, stating "***I spent the last 2 months of my life doing everything I humanly could to get Vioxx through with a good label***."

63. Weiner was correct in her assessment that CNBC's data was wrong. As *The Wall Street Journal* later reported, "[w]ithin three months of its launch, the Merck drug gained nearly a third of the brand-new market for 'Cox-2 inhibitors' … and within a year it had nearly half." In addition, VIOXX was "dominant" in Europe, where it had "beaten Celebrex to market in most countries despite filing later."

6. Merck's "Blockbuster" VIOXX Sales Grow From 2000 Through Mid-2004

64. By 2000, Merck was reaping more than $175 million in sales from VIOXX every month, a number that continued to grow during the Class Period. In total, Merck generated more than $2.1 billion from sales of VIOXX in 2000, which represented more than 10% of Merck's pharmaceutical sales.

65. In 2001, Merck generated more than $2.3 billion from sales of VIOXX, more than 11% of Merck's pharmaceutical sales.

66. In 2002, Merck generated more than $2.5 billion from sales of VIOXX, almost 12% of Merck's pharmaceutical sales.

67. In 2003, Merck generated more than $2.5 billion from sales of VIOXX, approximately 12.5% of Merck's pharmaceutical sales.

68. During the first six months of 2004, Merck generated more than $1.3 billion from sales of VIOXX.

7. Merck Shocks Investors By Pulling VIOXX From The Market

69. On September 30, 2004, Merck suddenly withdrew VIOXX from the market, after an external Data and Safety Monitoring Board overseeing a long-term Merck study to evaluate whether VIOXX could prevent colon cancer (the "APPROVe" trial) recommended that the trial be halted because patients taking VIOXX were significantly more likely than patients taking placebo to suffer heart attacks and strokes.

B. Unbeknownst to Investors, Merck Had Grave Concerns About VIOXX's Potential to Cause Heart Attacks and Strokes, Which Were Reinforced By Undisclosed Merck Data, Even Before It Launched VIOXX In May 1999

1. Merck Learns That VIOXX Upsets the Homeostatic Balance Between Prostacyclin and Thromboxane, and the Concerns Raised by Protocol 023

70. In 1996, Merck consultants Dr. Garrett FitzGerald and Dr. Francesca Catella-Lawson conducted a two-week clinical trial ("Protocol 023") for Merck that compared the effects of VIOXX, indomethacin (a traditional non-selective NSAID) and a placebo on the kidneys. They did this by measuring the urinary excretion of prostacyclin and thromboxane metabolites in thirty-six patients. The quantity of such metabolites in the urine is a proxy for the levels of prostacyclin and thromboxane in the bloodstream.

71. As discussed in ¶ 38 above, prostacyclin *widens* the blood vessels so that blood can flow more freely and potently *inhibits* blood clotting, whereas thromboxane *narrows* the blood vessels and potently *promotes* blood clots. These chemicals, which have opposite effects, exist in the human body in a natural balance referred to as homeostasis. An excess of

prostacyclin inhibits the body's ability to form blood clots in the case of a wound. An excess of thromboxane increases the risk of "thrombotic events" such as heart attacks and strokes, which occur as a result of blood clots forming in the body and obstructing blood vessels.

72. As set forth in the article reporting on the results of Protocol 023,[4] Dr. FitzGerald, Professor of Cardiovascular Medicine and Chairman of the Department of Pharmacology at the University of Pennsylvania, and Dr. Catella-Lawson, Assistant Professor in the Department of Medicine at the University of Pennsylvania, were aware that traditional NSAIDs had been found to inhibit both COX-1 and COX-2 and to reduce significantly the synthesis of both prostacyclin and thromboxane. Because they thought the synthesis of prostacyclin and thromboxane was related only to COX-1, however, they hypothesized that VIOXX -- which inhibited only COX-2 -- would have *no effect* on the urinary excretion of either prostacyclin or thromboxane metabolites.

73. Drs. FitzGerald and Catella-Lawson found that the results of Protocol 023 were inconsistent with this hypothesis. As they expected, VIOXX had no effect on urinary excretion of thromboxane metabolites but, contrary to their expectations, it *did* inhibit the urinary excretion of prostacyclin metabolites. Their findings suggested that COX-2 played a role in prostacyclin formation, and that VIOXX (as a COX-2 inhibitor) upset the homeostatic balance by inhibiting synthesis of the chemical that reduces clotting, widens blood vessels and promotes the flow of blood in the body (prostacyclin), without having any corollary impact on the chemical that narrows blood vessels and promotes clotting (thromboxane).

[4] The article, entitled "Effects of Specific Inhibition of Cyclooxygenase-2 on Sodium Balance, Hemodynamics, and Vasoactive Eicosanoids," was published in the May 1999 issue of the *Journal of Pharmacology and Therapeutics*.

74. Senior Merck scientists were very concerned by these findings. As noted above, an excess of thromboxane in the body could elevate the risk of thrombotic events such as heart attacks and strokes by causing blood clots to form and blood vessels to constrict, which together would increase the risk that the vital flow of blood to the brain or heart would be obstructed. Protocol 023 thus raised concerns that VIOXX might be "prothrombotic" -- *i.e.*, that it would cause thrombotic events such as heart attacks and strokes (and therefore have a safety profile that was worse than, or no better than, traditional NSAIDs, which were known to result in heightened incidence of a variety of gastrointestinal problems).

75. The results of Protocol 023 were published in the May 1999 issue of the *Journal of Pharmacology and Therapeutics* ("*JPAT*"). The authors of the article included Merck scientists Drs. Briggs Morrison, Barry J. Gertz, and Hui Quan. However, at Merck's insistence, the article downplayed the cardiovascular significance of Protocol 023's findings. Drafts of the article submitted by Drs. FitzGerald and Catella-Lawson to Merck in January and February 1998 (which were not disclosed to the public until after the Class Period) unequivocally stated that the results of Protocol 023 showed that "*[s]ystemic* biosynthesis of prostacyclin … *was* decreased," and that "[i]nhibition of [prostacyclin metabolites] by MK 966 [VIOXX] implies a *major role* for Cox-2 in *systemic* biosynthesis of prostacyclin in humans." An internal Merck memo dated February 18, 1998 from Dr. Morrison to his colleagues Drs. Nies, Gertz, Seidenberg, Quan and Bolognese (which also was not disclosed until after the Class Period) indicated Merck's "discomfort" with these conclusions, and proposed having a teleconference with Drs. FitzGerald and Catella-Lawson to change them. The final version of the article published in the May 1999 *JPAT* shows that the statements that Merck wanted to change were in fact greatly softened or eliminated. The final article stated only that "COX-2 *may* play a role in the systemic

biosynthesis of prostacyclin in healthy humans," and that "the implications of prostacyclin suppression *in vivo* are unclear." Consequently, publication of the May 1999 *JPAT* article did not cause analysts or investors to materially discount Merck's glowing statements about VIOXX's financial prospects.

2. Merck Cancels a Large VIOXX Clinical Trial in August 1997 Over Undisclosed Concerns It Would Show That VIOXX Caused Serious Adverse Cardiovascular Problems

76. Though Merck was able to successfully downplay the significance of Protocol 023 in the May 1999 *JPAT* article, internal Merck emails from 1997 (which were not disclosed to the public until after the Class Period) confirm that Merck scientists were greatly concerned that VIOXX caused heart attacks and strokes. As noted in ¶¶ 49 and 50, Merck had planned to initiate a large gastrointestinal outcomes trial before it obtained FDA approval for VIOXX. Such a trial had the potential to provide Merck with a very significant marketing advantage: if the results demonstrated that VIOXX was significantly less likely to cause serious GI problems than traditional NSAIDs, Merck would be able to sell VIOXX without the GI warning that the FDA required for both traditional NSAIDs and other COX-2 inhibitors (*i.e.*, Celebrex) until Celebrex demonstrated that it was GI-protective when compared to traditional NSAIDs. In the wake of Protocol 023, however, Merck also realized that such a trial had the potential to confirm that VIOXX had prothrombotic qualities -- which had the potential to be a disaster for Merck.

77. On February 23, 1997, defendant Reicin circulated a draft of the protocol for the proposed large scale VIOXX GI outcomes trial to her colleagues Drs. Briggs Morrison, Brian Daniels, Thomas Simon and Elliot Ehrlich. The proposed study protocol would have disallowed use of low dose aspirin (a traditional NSAID that inhibits both COX-1 and COX-2 enzymes and that was known to be cardio-protective). On February 25, 1997 at 8:23 a.m., Dr. Morrison, a

senior research and development executive at Merck who also was a co-author of the article that reported the results of Protocol 023, replied to all recipients of defendant Reicin's email, stating:

> [I] [w]ould allow low dose aspirin - I know this has been discussed to death but real world is everyone is on it so why exclude ***AND without COX-1 inhibition [provided by aspirin] you will get more thrombotic events and kill [the] drug.***

78. Data from a large scale GI outcomes trial showing that VIOXX users suffered "more thrombotic events" than naproxen users would indeed have likely "kill[ed] the drug" because VIOXX's commercial prospects rested entirely on the claim that it was safer to use than traditional NSAIDs, *i.e.*, on showing both that VIOXX was less likely to cause the GI problems associated with long-term use of traditional NSAIDs and that it did not cause other adverse side effects that outweighed its GI-protective qualities. If Merck generated data showing a reduction in adverse GI events but an increase in adverse CV events -- data which it would have to share with the FDA -- ***before*** the FDA had decided to approve VIOXX for marketing, the FDA almost certainly would have required Merck to undertake additional lengthy trials to establish VIOXX's cardiovascular safety (perhaps by a large scale trial against placebo) before the agency would allow VIOXX to be marketed.

79. On February 25, 1997, approximately two hours after Dr. Morrison sent his email, defendant Reicin replied to all recipients of Dr. Morrison's email stating:

> Low Dose Aspirin – I HEAR YOU! This is a no win situation! The relative risk of [more adverse GI events if we allow] even low dose aspirin may be as high as 2-4 fold. ***Yet, the possibility of increased CV [cardiovascular] events is of great concern- (I just can't wait to be the one to present those results to senior management!)***

In other words, although defendant Reicin was worried that allowing patients in the proposed large-scale GI outcomes trial to take aspirin would lead to more GI problems (because aspirin inhibits COX-1), she was "great[ly] concern[ed]" that excluding aspirin would lead to more

adverse cardiovascular events (because without COX-1 inhibition, there would be an excess of thromboxane in the bloodstream) which, in the words of her colleague Dr. Morrison, would "kill the drug."[5]

80. Accordingly, in the same email, defendant Reicin proposed that Merck design the gastrointestinal outcomes trial in a manner which would minimize the risk that it would generate significantly more adverse CV events among patients taking VIOXX in the study, and thereby hide the increased risk of heart attacks and strokes that VIOXX posed if it was prothrombotic by excluding from the trial patients who would be more vulnerable to its prothrombotic effects. Specifically, she stated:

> ***What about the idea of excluding high risk CV patients-*** ie those that have already had an MI [heart attack], CABG [coronary artery bypass grafting] or PTCA [angioplasty]? ***This may decrease the CV event rate so that a difference between the two groups would not be evident.*** The only problem would be –Would we be able to recruit any patients?

81. The reply sent the next day, February 26, 1997, by Dr. Brian Daniels, another senior Merck executive, to all recipients of defendant Reicin's email reflected his appreciation of the dilemma Merck faced. He stated: "***It is clear to me that the program will be severely hurt if the megatrial shows a win in PUBs [i.e., serious GI problems] and a loss in MI/CVA [i.e., heart attacks/other adverse cardiovascular events]***. That is what we are setting up by not allowing ASA [aspirin]."

82. As a result of these concerns, by no later than August 1997 Merck decided to ***cancel*** (or at least defer until FDA approval was already reasonably assured) its planned large-scale gastrointestinal outcomes trial. On August 13, 1997, Kyra Lindemann, a Merck

[5] Defendant Reicin's email also confirms that Merck's "senior management" was closely following developments relating to the testing of VIOXX and bringing it to market.

spokeswoman, circulated internally a draft press release and draft questions and answers concerning Merck's decision not to move forward with the gastrointestinal outcomes trial. ***Her email noted that these materials were "a bit awkward to write … because of the actual reasons for not proceeding with the study,"*** and that she had tried to "put a positive spin" on the decision not to move forward with the study by "emphasiz[ing] the fact that [Merck is] conducting [other] outcome studies" and by "convinc[ing]ly express[ing] confidence that our Phase III program is large enough to support these studies."

3. November 1997: Preeminent Medical Researcher and Merck Consultant Dr. John Oates Rejects Internal Merck Efforts to Rationalize the Adverse Implications of Protocol 023

83. While continuing to press forward with the development of VIOXX, Merck scientists were sufficiently concerned by the implications of Drs. FitzGerald and Catella-Lawson's Protocol 023 research, which suggested that VIOXX might be prothrombotic, that they searched high and low for an "alternative" explanation of Protocol 023's results.

84. For example, in the fall of 1997, Merck scientists Dr. Alan Nies (who was in charge of VIOXX's development) and Dr. Barry Gertz (who reported to Nies and was an author of the article reporting the results of Protocol 023) contacted Dr. John Oates, one of the world's foremost experts on prostacyclin and thromboxane, in the hopes of explaining away Protocol 023's results. Drs. Nies and Gertz asked Dr. Oates (who was then Senior Professor of Medicine and Professor of Pharmacology at Vanderbilt University School of Medicine) whether Protocol 023's finding that VIOXX inhibited the amount of prostacyclin metabolites in the urine could be attributed to an effect VIOXX was having on the kidney, rather than an effect VIOXX was having on the overall level of prostacyclin in the bloodstream. If VIOXX's effects were so limited, it would mean that VIOXX did not throw off the overall homeostatic balance between

prostacyclin and thromboxane in the bloodstream, and Merck's concerns that VIOXX was prothrombotic would be substantially alleviated.

85. Merck scientists had previously posed this question privately to Drs. FitzGerald and Catella-Lawson, who had responded that they did *not* believe that Protocol 023's results could be attributed to an effect VIOXX was having solely on the kidneys. By letter dated November 17, 1997, Dr. Oates gave a similar answer. Specifically, Dr. Oates privately advised Drs. Nies and Gertz that it was "quite unlikely" that the decreased prostacyclin metabolites could be attributed to an effect of VIOXX on the kidneys, because the "major sources of prostacyclin are exterior to the kidney, and that even in the kidney a predominant source would be expected to arise from a renal vasculature." Thus, Dr. Oates' opinion, rather than alleviating Merck's concerns about VIOXX's potential prothrombotic properties, only further supported Drs. FitzGerald and Catella-Lawson's conclusion that VIOXX disturbed the body's natural homeostasis between prostacyclin and thromboxane.

86. Internal Merck emails from this period also reflect Merck's continuing concerns about VIOXX's potential prothrombotic properties. For example, on January 13, 1998, defendant Scolnick emailed Tony Ford-Hutchinson, the head of Merck's team in Montreal that had developed the VIOXX molecule, and Bennett M. Shapiro, Merck's Executive Vice President of Basic Research, stating "***we all know what the issues are about MK 966 [VIOXX] and prostacyclin and thromboxane based on the urinary metabolite data***. I assume we are working VERY hard to clarify this in montreal [sic]….The data on prostacyclin in man seems clear. Can we try in animals? If it is true we MUST find out how it works."

4. Merck's Undisclosed Internal Analysis of Osteoarthritis Clinical Data Shows That Women Taking VIOXX Have A Statistically Significant 216% Increased Risk of Serious Adverse Cardiovascular Events Compared To Women Taking A Placebo

87. In February 1998, Merck prepared an internal analysis comparing the incidence of serious cardiovascular problems in patients taking VIOXX in Merck's Phase IIb/III VIOXX osteoarthritis trials (conducted as of December 15, 1997) to the incidence of serious cardiovascular problems among patients taking a placebo in certain other large clinical trials that Merck had undertaken in connection with its PROSCAR and FOSAMAX drugs.[6] In the Introduction and Background section of the analysis, Merck scientist Dr. Doug Watson (the lead author of the analysis) noted that the impetus for the analysis was Drs. FitzGerald and Catella-Lawson's findings in Protocol 023, which had "raised concern about the potential for VIOXX to predispose to thrombotic cardiovascular events," as well as the results of a small Merck clinical study (Protocol 010) in which patients taking VIOXX "had more clinical 'Cardiovascular' AEs [adverse events] than the placebo group." The purpose of the internal February 1998 Merck analysis was to determine whether Merck needed to change the design of its clinical trials for VIOXX to provide for "more formal monitoring of the risk of thrombotic CV serious adverse events (SAEs) with VIOXX."

88. Because Merck did not know at the time of analysis which patients in the Phase IIb/III VIOXX osteoarthritis trials were using VIOXX as opposed to a comparator NSAID or placebo, it included ***all*** patients in the VIOXX osteoarthritis trials in the VIOXX arm of the analysis. The internal 1998 Merck analysis thus compared all patients in the Phase IIb/III VIOXX osteoarthritis trials (including those who were taking comparator NSAIDs or placebos

[6] PROSCAR is used to treat enlarged prostate; FOSAMAX is used to treat or prevent osteoporosis.

rather than VIOXX) to all patients who were known to have taken only placebo in the PROSCAR and FOSAMAX trials. Consequently, if VIOXX users had higher rates of thrombotic events, such an increase would be reduced or perhaps even masked entirely by the inclusion of patients taking other NSAIDs or placebo in the "VIOXX arm" of the comparative analysis.

89. Nonetheless, as Dr. Gurkipal Singh, then-Adjunct Clinical Professor of Medicine at Stanford University School of Medicine, stated in public testimony before the United States Senate Committee on Finance on November 18, 2004 -- after Merck had withdrawn VIOXX from the market -- Merck's internal February 1998 analysis "concluded that men taking VIOXX had a 28% greater risk [of serious cardiovascular adverse events] (not statistically significant), ***but in women, the risk was more than double (216%, statistically significant) compared to people not taking any drug in other Merck studies.***"[7] Dr. Singh added that "[t]o the best of my knowledge, these data were never made public" and that ***"[t]his is when a public scientific discussion of the pros and cons of the medication should have started."***

90. The internal February 1998 Merck analysis did not become a starting point for a scientific debate about VIOXX's safety, however, because instead of making public these results that could have "kill[ed] the drug," Merck (which was under tremendous pressure to get VIOXX to market ahead of Celebrex) went out of its way -- and outside the bounds of accepted medical research practices -- to avoid disclosing the fact that Merck's own data indicated that VIOXX caused at least a 216% statistically significant increase in serious cardiovascular events among women compared to placebo. Merck attempted to rationalize the data by speculating that the rate

[7] For the reasons set forth in ¶ 88 above, it seems likely that it would have been more accurate for Dr. Singh to state that Merck had found that men had *at least* a 28% greater risk of serious cardiovascular adverse events, and that women had *at least* a statistically significant 216% greater risk of serious cardiovascular adverse events, compared to people taking a placebo.

of serious cardiovascular events among the large population of women taking placebo (over 4,400 women) was "atypically low," and that it was this "atypically low" rate of serious adverse cardiovascular events in women in the placebo group -- rather than a statistically significant increased cardiovascular risk from VIOXX -- that was responsible for the statistically significant difference in cardiovascular results obtained. Relying on this clearly unscientific, "heads I win, tails you lose" line of reasoning, the February 1998 internal Merck analysis purported to reach the astounding conclusion that the incidence rates of serious cardiovascular events in the VIOXX trials "appear roughly consistent with what would be expected in the general population," and that Merck therefore did not need to change its study protocols to provide for better monitoring of cardiovascular risks with VIOXX. This conclusion was so obviously flawed that no reasonable scientist could have relied upon it other than by recklessly disregarding the self-serving and non-scientific assumptions on which it was based. The results of Merck's internal February 1998 analysis did not become public until after the Class Period.

5. Merck Attempts to "Manage" Concerns About VIOXX's Cardiovascular Safety as It Nears Completion of Its New Drug Application for VIOXX in 1998

91. In April 1998, Dr. Alan Nies (the senior Merck scientist who had been corresponding with Dr. Oates about Protocol 023's problematic findings) prepared a report on VIOXX for Merck's Board of Scientific Advisors, a board comprised of external scientists that is supposed to act as an independent check on the biases of Merck scientists, and which was scheduled to hold its annual meeting in May 1998. Recognizing that its Board of Scientific Advisors might put the brakes on Merck's rush to have VIOXX beat Celebrex to market, the internal and non-public report prepared by Dr. Nies did not disclose the serious concerns that Merck scientists and executives had about VIOXX's potential to cause thrombotic events such as heart attacks and strokes. Indeed, the Merck report prepared by Dr. Nies made no mention of

any issues concerning cardiovascular safety until page 10 of the 11 page report, in a section entitled "Prostacyclin Metabolism." That section discussed Protocol 023's findings that VIOXX inhibited prostacyclin but not thromboxane, but represented that Merck's internal February 1998 analysis of VIOXX osteoarthritis data did not suggest any cause for concern. However, Dr. Nies' report did ***not*** disclose to the Board of Scientific Advisors the data from Merck's February 1998 internal analysis showing a ***statistically significant 216%*** greater chance of suffering a serious cardiovascular event among female patients in osteoarthritis trials involving VIOXX and a 28% greater chance of suffering such an event among male patients, nor did it disclose the clearly unscientific assumption on which Dr. Watson had concluded that this data was not significant, even though members of the Board of Scientific Advisors would have certainly found such information highly relevant in assessing VIOXX's alleged safety.

92. Nonetheless, Merck's external Board of Scientific Advisors was still troubled by VIOXX's potential cardiovascular effects given its impact on prostacyclin. Indeed, more than half of the Board's internal and non-public Programmatic Review of the VIOXX program (7 out of 13 pages) was addressed to Protocol 023's findings that VIOXX inhibited prostacyclin but not thromboxane, and the potential implications of those findings. Noting that "[p]rostacyclin is the most potent endogenous inhibitor of platelet aggregation [clotting]" and that "it also potently inhibits the development of ischemic ventricular fibrillation [cardiac arrest]," the Board emphasized that Protocol 023's finding that VIOXX reduces the urinary excretion of the prostacyclin metabolite raised the possibility that ***"[b]y removing this potent inhibitor of platelet aggregation, the probability that a coronary plaque rupture would lead to myocardial infarction [heart attack] or ischemic ventricular fibrillation [cardiac arrest] is enhanced.***" Accordingly, contrary to the recommendation contained in Merck's internal February 1998

analysis (which was never shown to the Board), Merck's external advisory Board "proposed that coronary events be predetermined endpoints [*i.e.*, a primary focus of the data being collected] in all future controlled trials with Vioxx" and "that these endpoints be assessed by a uniform set of criteria so that meta-analysis of coronary and cerebrovascular events from all of these trials can be performed."

93. Actively exploring whether VIOXX in fact caused thrombotic events, with the attendant risk that it might "kill the drug," was not something that Merck wanted to do. Instead, Merck continued to rush forward with its efforts to get VIOXX on the market in an effort to keep pace with Celebrex, and Merck effectively shrugged off the serious concerns raised by Dr. Oates and Merck's Board of Scientific Advisors. Thus, in a September 29, 1998 handwritten memo, Dr. Nies informed his Merck colleagues Drs. Barry Gertz and Reynold Spector (head of clinical sciences at Merck) that he had spoken to Dr. Oates -- who had proposed studying VIOXX in patients with atherosclerosis and elevated thromboxane metabolite excretion -- and had told him that Merck "would not be doing any [such] clinical studies at this time."

94. As noted in ¶ 76 above, Merck submitted its New Drug Application for VIOXX to the FDA on November 23, 1998. In the months before its approval, Merck officials publicly spoke of VIOXX only in glowing terms. For example, on December 9, 1998, at Merck's annual analyst meeting, defendant Scolnick boasted: "Short-term high dose, long-term low dose, it's a wonderful drug . . . VIOXX has lived up to our highest expectations." Merck and the Officer Defendants thus conditioned the market to believe that VIOXX would be a blockbuster hit, never disclosing the Company's "great concern" about VIOXX's potential to cause thrombotic events such as heart attacks and strokes, or the growing body of internal clinical data that fueled those concerns.

C. May 21, 1999 (The First Day of the Class Period): Merck Heralds the FDA's Approval of VIOXX While Continuing to Conceal Its "Great Concern" And Related Adverse Information About VIOXX's Safety

95. On May 21, 1999, the first day of the Class Period, Merck issued a press release announcing that VIOXX "has received marketing approval from the U.S. Food and Drug Administration. VIOXX has been approved for the relief of osteoarthritis (OA), management of acute pain in adults, and treatment of menstrual pain (primary dysmenorrheal)." With respect to the drug's side effects, the press release stated: "The most common side effects reported in clinical trials with VIOXX were upper-respiratory infection, diarrhea and nausea."

96. Merck and the Officer Defendants did not disclose to investors their "great concern" that VIOXX caused serious side effects, such as heart attacks and strokes. Although this concern had led Merck to cancel its large-scale GI outcomes study in 1997, Merck and the Officer Defendants decided not to disclose this concern or that it was based on their knowledge that (a) VIOXX upset the homeostatic balance between prostacyclin and thromboxane by inhibiting prostacyclin but not thromboxane; and (b) Merck's internal February 1998 analysis, which was not disclosed to the public until after the Class Period, showed that patients in VIOXX clinical trials had higher rates of serious adverse cardiovascular events compared to patients taking placebo, including a ***statistically significant increase of at least 216% among women***.

D. March 2000: Merck Is Finally Forced to Undertake a Large Gastrointestinal Outcomes Trial (VIGOR), Which Confirms the Company's Belief That VIOXX Is Prothrombotic

97. In January 1999, with FDA approval of VIOXX within sight, Merck had finally begun its long-delayed large gastrointestinal outcomes trial, entitled VIOXX Gastrointestinal Outcomes Research ("VIGOR") -- the trial that Merck knew was necessary to obtain a label stating that VIOXX had a lower incidence of significant GI complications than comparator

NSAIDs, but which Merck had previously cancelled in August 1997 out of concern that it would confirm that VIOXX was prothrombotic. By early 1999, Merck had been effectively forced to undertake such a study by news that Pfizer and Monsanto/Searle had already begun a similar study with respect to Celebrex, entitled Celebrex Long-Term Arthritis Safety Study ("CLASS"). If CLASS could establish that Celebrex caused significantly fewer serious GI problems than traditional NSAIDs and Merck could not produce similar study results in a comparable large-scale trial, VIOXX's competitive position vis-à-vis Celebrex would be severely jeopardized.

98. Moreover, because the results of the large scale GI outcomes trial would not be reported to the FDA until *after* VIOXX was approved for marketing, a post-FDA approval finding that VIOXX users incurred a significantly higher rate of heart attacks would not pose nearly as big a danger to Merck. More particularly, as long as Merck could proffer some plausible alternative explanation for such results -- such as an alleged cardioprotective effect of the comparator drug naproxen -- the FDA would have to go through a burdensome regulatory process before it could *remove* VIOXX from the market. In other words, by delaying the start of its large GI outcomes trial so that its results would not become available until after initial FDA approval was secured, Merck was able to reduce substantially the risk that the results, even if they suggested that VIOXX might be prothrombotic, would "kill the drug."

99. Moreover, Merck also intentionally designed VIGOR to minimize the likelihood that the results would show that VIOXX was prothrombotic. Consistent with defendant Reicin's 1997 proposal that Merck exclude patients at high risk of suffering a serious cardiovascular event so as to minimize the odds of producing adverse study results, Merck excluded from VIGOR all patients who were taking low-dose aspirin to prevent cardiovascular problems -- the very class of predominantly older patients who suffer from osteoarthritis and were most likely to experience

adverse cardiovascular events if VIOXX were prothrombotic. Merck also initially chose not to gather data about adverse cardiovascular events as a designated endpoint (primary focus) of this trial -- contrary to the recommendation of Merck's Board of Scientific Advisors that "coronary events be predetermined endpoints in all future controlled trials with Vioxx." Merck also chose not to name a cardiologist to VIGOR's Data and Safety Monitoring Board ("DSMB"), which was the panel established to monitor the unblinded results of VIGOR in order to protect the safety of trial participants.

100. Merck enrolled more than 8,000 patients in VIGOR, with 4,047 being given VIOXX and 4,029 being given naproxen (a traditional NSAID). It appointed to the DSMB Drs. Michael Weinblatt, David Bjorkman, James Neaton, Alan Silman, Roger Sturrock, and Deborah Shapiro.

101. Contrary to the customary practice of naming to a DSMB only unbiased outside scientists, at least half of the members of VIGOR's DSMB had substantial Merck-related conflicts of interest. As later revealed on National Public Radio's June 8, 2006 *All Things Considered* program, Dr. Weinblatt, the head of the DSMB, and his wife owned Merck stock worth $73,000. Dr. Bjorkman served as a Merck consultant during the period that VIGOR was ongoing. And Dr. Shapiro, who filled the critically important role of VIGOR's *unblinded* statistician, was the most conflicted of all, as she was a full-time Merck scientist who reported to defendant Scolnick.

102. By the beginning of September 1999, patients in the VIGOR study who were taking VIOXX had, compared to patients taking naproxen, suffered substantially more serious cardiovascular events in general (36 in VIOXX users, 16 in naproxen users), substantially more cardiovascular events leading to discontinuation of treatment (*i.e.*, patients quitting the study) (32

in VIOXX users, 17 in naproxen users), and almost twice as many deaths (11 in VIOXX users, 6 in naproxen users).

103. By the beginning of November 1999, these trends had continued and, in the case of serious adverse cardiovascular events leading to discontinuation or death, gotten significantly worse for VIOXX. For example, by November 1999, patients taking VIOXX had substantially more serious cardiovascular events (52 in VIOXX users, 29 in naproxen users), more than twice as many cardiovascular events leading to discontinuation (40 in VIOXX users, 17 in naproxen users) and almost three times as many deaths (16 in VIOXX users, 6 in naproxen users). The minutes of the DSMB's November 17, 1999 meeting reflect that these "differences between the treatment groups were … significant beyond the level of chance." Nonetheless, the supposedly independent VIGOR DSMB, in consultation with Merck scientist Shapiro, decided not to stop the VIGOR study -- a result which would have been devastating to Merck. Rather, the DSMB noted its concern about this data and scheduled a special interim meeting for December 20, 1999 at which it would "focus on deaths and cardiovascular AEs [adverse events]."

104. The minutes of the DSMB's December 20, 1999 meeting state that "[t]he members noted that the trends previously observed [concerning deaths and cardiovascular adverse experiences] continued." Nonetheless, the VIGOR DSMB once again decided not to stop the VIGOR study.

105. The minutes of the DSMB's December 20, 1999 meeting further reflect that members of the DSMB were surprised to learn that Merck had not yet prepared a data analysis plan for adverse cardiovascular events despite the fact that "the VIGOR Data Analysis Plan states that a data analysis plan would be developed for these events." The DSMB resolved to write a letter to defendant Reicin requesting "that an analysis plan be developed to analyze

serious cardiovascular events in the VIGOR trial separately from any other planned analyses of these data," and that "these events be adjudicated blinded" to avoid any bias in interpretation. The DSMB noted that it was "not recommending a change to the trial conduct, simply that a prespecified plan be accomplished."

106. Merck's failure to develop a data analysis plan for adverse cardiovascular events was not an innocent oversight but the product of ***a conscious decision by senior management***. In a January 14, 2000 email, Dr. Watson, the Merck scientist who had prepared Merck's internal February 1998 analysis of serious adverse cardiovascular events among osteoarthritis patients who had used VIOXX, wrote:

> [T]he plan approved by [Merck's] CDOC [Clinical Development Oversight Committee] was to include VIGOR with other blocks of studies for an analysis later. [Dr.] Jim [Bolognese] had the assignment to develop a DAP [Data Analysis Plan] for the analysis. ***Since then we (Jim and I) have been instructed by CDOC and senior management to not do so, and that comparisons with other treatments are not to be made.***

107. On January 21, 2000, Merck scientist and VIGOR DSMB member Dr. Shapiro informed her fellow DSMB members that Merck had declined their request to perform a separate analysis of VIGOR's cardiovascular data. Dr. Weinblatt, on behalf of the DSMB, pushed back against Merck's refusal to perform such an analysis. By letter dated January 24, 2000 to defendant Reicin, Dr. Weinblatt wrote that "An analysis of these cardiovascular data must be provided separately for VIGOR as part of the study report."

108. On February 7, 2000, Merck reluctantly agreed to analyze VIGOR's cardiovascular data, but to include only events reported through February 10, 2000 -- a cut-off date that was one month earlier than the cut-off date for GI data -- in its initial analyses. Dr. Weinblatt, on behalf of the DSMB, accepted Merck's proposal to use different cut-off dates for cardiovascular and GI data even though use of different cut-off dates was inconsistent with

customary scientific practice. Shortly thereafter, Dr. Weinblatt accepted Merck's offer to pay him $5,000 a day to sit on a Merck Advisory Board. Over the next two years, Merck paid him $60,000 pursuant to that agreement.

109. Reports of the DSMB's insistence on an analysis of VIGOR's cardiovascular data had filtered through Merck, increasing concerns that the data would show precisely what Merck most feared: that VIOXX caused thrombotic events. Indeed, on February 11, 2000, one day after Merck's cut-off date for inclusion of cardiovascular adverse event data (and just a month before the cut-off date for the inclusion of GI adverse event data), defendant Scolnick sent his subordinate Dr. Shapiro -- the unblinded statistician for the VIGOR trial -- an email which attached a copy of a Wall Street analyst report suggesting that momentum was swinging toward Celebrex in its battle with VIOXX. The email, which clearly suggests that Scolnick intended to try to influence Dr. Shapiro's analysis of VIGOR's cardiovascular data, reads as follows:

> Deborah Please read this story. It is my understanding that you are the unblinded statistician in our Vigor study. In the last few days we are being pounded by stories like this. As with the key issue with aggrastat when Snappin and I had to make a decision ***as soon as you know what the answer is I would like a confidential meeting with you. This situation cannot simply follow the 'book' ways of my knowing.*** Please let me know when I can talk to you confidentially. You can reach me when this time comes at work at home [redacted] by voicemail (private) or anywhere by email- I am the only one who listens to my voice mail or email. Thanks I hope your lucky rabbit's foot is as good as it was with mevacor afcaps/ Ed Scolnick

110. On March 9, 2000, defendant Scolnick was informed of the preliminary results of the VIGOR trial. The data showed that patients taking VIOXX suffered ***significantly*** more heart attacks and deaths than the patients taking naproxen. In response, on March 9, 2000, Scolnick emailed Shapiro, Nies, and defendant Reicin as follows:

> To all: I just received and went through the data. … ***The CV [cardiovascular] events are clearly there***. … It is a shame but it is

> a low incidence and ***it is mechanism based as we worried it was. [Dr. John] Oates and Alan [Nies] and Barry [Gertz] were right about the metabolite meanings ie urine Pg [prostaglandin] data.***

Defendant Scolnick's reference to the cause of the cardiovascular events being "mechanism-based as we worried it was," and his statement that Drs. Oates, Nies and Gertz "were right" about the meaning of the urine prostaglandin data, was an admission that he believed that VIOXX was prothrombotic, and that the reason it was prothrombotic was because it inhibited prostacyclin without inhibiting thromboxane.

E. The "Naproxen Hypothesis": Merck Falsely Represents That It Believes That the Higher Incidence of Adverse CV Events Among VIOXX Users in the VIGOR Trial Is Attributable To Purported Cardioprotective Properties of Naproxen Rather Than Prothrombotic Properties of VIOXX

111. Although the VIGOR results confirmed Merck's and its senior scientists' belief that VIOXX was prothrombotic, Merck and the Officer Defendants also knew that publicly admitting this fact would precipitate a financial disaster for Merck, resulting in the loss of its investment in VIOXX and billions of dollars in potential revenue from VIOXX.

112. Thus, rather than acknowledge their belief that the statistically significant difference in the number of heart attacks in the VIGOR trial was "mechanism based" and attributable to VIOXX's prothrombotic properties, Merck and the Officer Defendants decided to attempt to lead both the medical and Wall Street investor communities to believe that the VIGOR CV results were most likely attributable to some cardioprotective effect of naproxen (*i.e.*, the "naproxen hypothesis").

113. In the days that followed the internal distribution of VIGOR's results within Merck, senior Merck scientists and consultants worked around the clock to try to find meaningful support for the theory that naproxen was cardioprotective. They failed. On March 13, 2000 at 1:20 a.m., defendant Reicin emailed defendant Scolnick and Dr. Nies:

> Alan and Ed:
>
> Below is attached the abstract for the ***only study*** I could find which assessed the potential cardioprotective effects of an NSAID.
>
> Alise

The abstract was for a seven year old article from the July 1993 issue of *European Heart Journal* entitled "Evaluation of Flurbiprofen for Prevention of Reinfarction and Reocclusion After Successful Thrombolysis or Angioplasty in Acute Myocardial Infarction."

114. The 1993 *European Heart Journal* article reported that a small-scale study (464 patients in total) in France among patients who had been successfully treated for a heart attack within six hours of its onset showed that patients who had taken flurbiprofen, a traditional NSAID, had lower risks of suffering a second heart attack or needing a coronary angioplasty or bypass graft than patients who took a placebo. The article speculated that flurbiprofen might offer advantages over aspirin, but cautioned that comparable efficacy needed to be established. ***The article had nothing to say about naproxen, as naproxen was not used in that study.***

115. Over the next two weeks, Merck continued to search for any support for its naproxen hypothesis. In a March 24, 2000 email, Dr. FitzGerald (the Merck consultant who had conducted Protocol 023) sent Dr. Alan Nies (the Merck scientist who was in charge of developing VIOXX) "the best comparative clin[ical] data on MI [heart attack] and NSAIDs" of which he was aware. That same day, Dr. Nies forwarded Dr. FitzGerald's email to defendant Reicin and fellow senior Merck scientist Dr. Gertz.

116. Dr. FitzGerald's March 24, 2000 email provided data from an unpublished non-Merck study, involving an analysis of more than 164,000 patients, which sought to estimate and compare the effects of aspirin and non-aspirin NSAIDs in preventing heart attacks. FitzGerald's email contained specific data for aspirin, naproxen, ibuprofen, and diclofenac individually, as

well as data for naproxen, ibuprofen and diclofenac combined. As Dr. FitzGerald's email went on to point out, although the data confirmed that aspirin significantly reduced the risk that patients might suffer a first, nonfatal heart attack, ***the other NSAIDs, including naproxen, "had no significant effect," either individually or combined, on the risk of suffering a heart attack.*** Dr. FitzGerald noted that "amongst these INSIGNIFICANT effects [capital letters in original], naproxen looked best," but reiterated that "there were no sig[nificant] diff[erence]s between the nsaids."

117. Dr. FitzGerald's non-public March 24, 2000 email therefore failed to provide any reasonable basis for Merck to claim that naproxen was cardioprotective, and in fact ***undercut*** that claim. Indeed, Merck knew, based on Dr. FitzGerald's email, that the best scientific evidence available showed that naproxen "had no significant effect" in preventing a heart attack.

118. The data on naproxen contained in Dr. FitzGerald's March 24, 2000 email were not disclosed to the market. The results of the study referenced in this email were later published in the July 2000 issue of *Epidemiology* in an article entitled "Differential Effects of Aspirin and Non-Aspirin Nonsteroidal Antiinflammatory Drugs in the Primary Prevention of Myocardial Infarction in Postmenopausal women." However, unlike Dr. FitzGerald's email, which contained the specific data for naproxen, ibuprofen, and diclofenac individually, the *Epidemiology* article reported only the *aggregate* data for a group of *unspecified* non-aspirin traditional NSAIDs. The article did not even mention that naproxen was one of the traditional NSAIDs considered in the study. Thus, Merck had data on naproxen (which Dr. FitzGerald's March 24, 2000 email indicates he privately received from the study's author) that was not available in the published version of the study.

119. Notwithstanding its failure to find any meaningful scientific support for its "naproxen hypothesis" (and notwithstanding the non-public information in its possession that contradicted that hypothesis), on March 27, 2000 Merck issued a press release designed to lead the public to believe that the "naproxen hypothesis" was the most likely explanation for VIGOR's CV results, and that VIOXX did not cause heart attacks or strokes. After lauding VIGOR's GI results, Merck's press release stated:

> In addition, significantly fewer thromboembolic events were observed in patients taking naproxen in this GI outcomes study, ***which is consistent with naproxen's ability to block platelet aggregation***. This effect on these events had not been observed previously in any clinical studies for naproxen. ***VIOXX, like all COX-2 selective medicines, does not block platelet aggregation and therefore would not be expected to have similar effects.***

The press release further stated:

> An extensive review of safety data from all other completed and ongoing clinical trials, as well as the post-marketing experience with VIOXX, showed no indication of a difference in the incidence of thromboembolic events between VIOXX, placebo and comparator NSAIDs. Further analyses are ongoing, and final results of the GI outcomes study with VIOXX will be presented at peer-reviewed medical meetings this year.

120. Merck's March 27, 2000 press release was intentionally designed to mislead investors, patients and doctors into believing that it clearly was more likely than not (a) that VIOXX had no impact on a user's risk of suffering a heart attack, stroke or other adverse CV event and (b) that the results of VIGOR did not impair VIOXX's commercial prospects and viability. However, as set forth above, in fact Merck and the Officer Defendants (a) had concluded that VIOXX was prothrombotic, and (b) in searching for information that might support the "naproxen hypothesis" had found only additional, non-public information that undercut their hypothesis.

121. Merck's March 27, 2000 press release was widely reported and analyzed in the press and by securities analysts. In the wake of this press release, market analysts and members of the press understood that, in the absence of more definitive studies, it was still possible that VIOXX was prothrombotic, but most repeated and adopted Merck's "naproxen hypothesis," which was propped up by Merck's false representation that there was "no indication" from Merck's other clinical data that VIOXX might be prothrombotic.

122. Although it was widely reported that Merck's "naproxen hypothesis" was the most likely explanation for the CV events in VIGOR, some financial analysts and journalists suggested that the alternative explanation -- that VIOXX was prothrombotic -- might be equally plausible. In response to "speculative news reports," on April 28, 2000 Merck issued a press release entitled "Merck Confirms Favorable Cardiovascular Safety Profile of VIOXX" that stated:

> Extensive review of data from the completed osteoarthritis trials and on-going clinical trials with VIOXX, as well as post-marketing experience with VIOXX, have shown no difference in the incidence of cardiovascular events, such as heart attack, among patients taking VIOXX, other NSAIDs and placebo.

Merck also reaffirmed its professed belief in its "naproxen hypothesis," stating that the difference in the rate of heart attacks found in VIGOR was "consistent with naproxen's ability to block platelet aggregation." As was the case with Merck's March 27, 2000 press release, however, the April 28, 2000 press release was materially false and misleading because it failed to disclose Merck's lack of good faith belief in its naproxen hypothesis, and the totality of the information upon which its actual belief was based, including, *inter alia*, the results of Merck's internal February 1998 analysis (which showed at least a statistically significant 216% greater risk of serious adverse cardiovascular events among women taking VIOXX as compared to women taking placebos in other Merck studies) and the results of Protocol 023.

123. Defendants also looked for ways to purportedly bolster their claim that naproxen had reduced cardiovascular risk (and VIOXX had not increased it). To that end, Defendants publicly claimed in Merck's May 24, 2000 press release and the November 23, 2000 article in the *New England Journal of Medicine* formally reporting the VIGOR results (and listing defendant Reicin as an author) that 4% of the patients were improperly enrolled in VIGOR as they were at especially high risk for adverse cardiovascular events, and that the presence of this subpopulation in the VIGOR study was driving the extraordinary discrepancy observed between the number of heart attacks suffered by patients that took VIOXX compared to patients that took naproxen in VIGOR.

124. In accordance with the VIGOR protocol, all of the patients enrolled in VIGOR had been screened for cardiovascular risk by independent investigators at the outset of the study, and any patients who were indicated for low-dose aspirin prophylaxis had been excluded. After learning the VIGOR results, however, Merck contradicted the judgment of the independent study clinicians, and concluded that 4% of the VIGOR patients were purportedly indicated for low-dose aspirin prophylaxis and had been admitted to the VIGOR study in violation of the protocol (and were so-called "protocol violators"). On May 24, 2000, Merck issued a press release concerning the VIGOR results that reiterated the naproxen hypothesis and claimed that this 4% subgroup of patients experienced a higher rate of heart attacks than the remaining 96% of the VIGOR population, and that "[a]mong the 96 percent of patients in VIGOR who were not candidates for low-dose aspirin for such cardioprotection, there was no significant difference in heart attack rates – 0.1 percent among patients taking naproxen and 0.2 percent among patients taking Vioxx."

125. Merck's May 24, 2000 statement was materially misleading because it communicated to the public that this supposedly higher-risk "aspirin-indicated" subgroup faced a qualitatively different cardiovascular risk than the rest of the VIGOR population, and that the incidence of adverse cardiovascular events within that subgroup was quantitatively different in a meaningful and demonstrable way. Thus, Merck claimed that the result observed in VIGOR was entirely consistent with the naproxen hypothesis. According to Merck, administration of potent antiplatelet agents to rheumatoid arthritis patients would normally reduce the incidence of CV events by a certain amount and, when such an agent is administered to a group of patients at extraordinary risk for such events, differences in event rates would be expected to increase dramatically.

126. Before and after Merck issued its May 24, 2000 statement, Merck internally recognized that the "4% claim" was incorrect and unreliable. Merck employees that reviewed a May 11, 2000 draft paper to report on the VIGOR results, which advanced Merck's claim concerning the effect of the 4% of the VIGOR population on the magnitude of the observed difference in between-arm cardiovascular events, commented concerning that claim, "***give me a break***[. O]ne barely has enough power (with just 21 events) to detect an overall difference with so few events." In other words, VIGOR barely had enough statistical power to detect the overall difference in heart attacks across the entire study, and it would have thus lacked statistical power to compare the number of events within the 4% and 96% subgroups against each other. The reviewer also commented that "***this is a stretch for a post hoc analysis*** – there is considerable overlap in the CI's [confidence intervals]," which undermined the notion that the 4% and 96% subgroups were meaningfully different. Despite these criticisms of the 4% analysis, Merck proceeded to publish its May 24, 2000 press release containing the analysis and reiterated it in

the November 23, 2000 *New England Journal of Medicine* paper formally publishing the VIGOR results, which listed Reicin as an author.

127. In addition, in an internal presentation of the "VIGOR Final Results" in June of 2000, Merck statisticians acknowledged, "clinical has made much of the fact that if the ***protocol violators*** [i.e., the 4% of the VIGOR population who purportedly should have been aspirin-indicated] had been excluded, we would not have had any issues with the cardiovascular data. However, ***statistically these relative risks [for cardiovascular events on VIOXX versus naproxen in the 4% subgroup and in the 96% subgroup] are not different***. That may be because the aspirin indicated group is so small but we cannot tell that here."

128. Likewise, according to notes that Deborah Shapiro, a Director of Statistics at Merck who served as the unblinded statistician on the VIGOR trial, took at a non-public meeting with Merck's outside consultants on October 18, 2000, the consultants told defendant Reicin and other Merck employees that it was "***misleading to emphasize aspirin indication*** since no significant heterogeneity" – *i.e.*, there was not a sufficient finding that the characteristics of the 4% subgroup were sufficiently different from the 96% subgroup. Shapiro in fact testified in this case on March 6, 2013 that she understood this to mean that "***you can't just pull out that four percent***" as Merck did in its May 24, 2000 press release and the November 23, 2000 *NEJM* article, because "there was no significant difference in treatment effect [and] the relative risk was not significantly different in the two subgroups." Merck's May 24, 2000 press release was thus materially false and misleading.[2] Yet, Merck published that analysis in the May 24, 2000 press

[2] Indeed, numerous members of the Merck Research Laboratories Communications Department, including its head, Dr. Laurence Hirsch, were made aware, at least as early as January 2001, that "MRL [Merck Research Laboratories] was advised by their consultants not to use [the rates in the 96% non-aspirin-indicated patients in VIGOR] **– *too shaky***."

release and in the November 23, 2000 *New England Journal of Medicine* article publishing the VIGOR results without mention of the adverse internal information.

129. On May 24, 2000, Merck gave a formal presentation of the VIGOR study data at a major digestive disease medical conference. At that conference, Merck again reiterated its naproxen hypothesis and touted VIOXX's purported safety. Market analysts again reacted favorably to these further reassurances, while still acknowledging that the naproxen hypothesis was not proven.

130. Throughout the Class Period, Merck continued to offer the naproxen hypothesis as the most likely explanation for VIGOR's cardiovascular results. For example, in a February 2001 presentation before the FDA's Arthritis Advisory Committee concerning Merck's request to amend the label for VIOXX to reflect the positive GI results from the VIGOR study, defendant Reicin reiterated that it was Merck's belief that "the decreased cardiovascular events with naproxen in VIGOR is consistent with [naproxen's] potent anti-platelet effects."

131. On August 22, 2001, the *Journal of the American Medical Association (*"*JAMA*"*)* published an article, authored by cardiologists Eric J. Topol, Steven E. Nissen, and Debabrata Mukherjee of the Cleveland Clinic, entitled "Risk of Cardiovascular Events Associated With Selective COX-2 Inhibitors," which reported the results of a study of VIOXX and Celebrex (the "Cleveland Clinic Study"). The *JAMA* article stated that "[c]urrent data would suggest that use of selective COX-2 inhibitors might lead to increased cardiovascular events," and further noted: "The available data raise a cautionary flag about the risk of cardiovascular events with COX-2 inhibitors."

132. On August 21, 2001, the day before the *JAMA* article was published, *Bloomberg News* reported that, in anticipation of the publication of the Cleveland Clinic Study findings,

Merck, through its Senior Director of Cardiovascular Clinical Research, Laura Demopoulos, had commented: "We already have additional data beyond what they cite, and the findings are very, very reassuring. VIOXX does not result in any increase in cardiovascular events compared to placebo." Merck's August 21, 2001 statement was intended to, and did, reassure the market concerning VIOXX's purported lack of cardiovascular risks.

133. On August 23, 2001, the day after the release of the *JAMA* article, Merck issued a Company press release stating that "the Company stands behind the overall and cardiovascular safety profile . . . of VIOXX." Immediately after the publication of the *JAMA* article, Merck also sent, by Federal Express, "Dear Doctor" letters to physicians throughout the country disparaging the article as "not based on any new clinical study" and assuring the physicians that Merck "stands behind the overall and cardiovascular safety profile" of VIOXX.

134. News and analyst reports following the release of the *JAMA* article reinforced the "naproxen hypothesis" as the most likely interpretation of the VIGOR CV data and disparaged the *JAMA* article. For example, on August 22, 2001, Credit Suisse First Boston reported that:

> The JAMA researchers themselves point out several significant limitations in their study . . . .We note that the VIGOR trial did not include low-dose aspirin, and that the control drug (naproxen) is known to possess a cardio-protective, anti-platelet effect. This makes it extremely difficult to determine whether the difference in cardiac events seen in VIGOR results from a naproxen "benefit" or a Vioxx "liability."

135. On September 21, 2001, the FDA posted on its website a warning letter that its Division of Drug Marketing, Advertising, and Communications ("DDMAC") had sent to Merck four days earlier regarding its marketing and promotion of VIOXX. The DDMAC Letter stated:

> You have engaged in a promotional campaign for VIOXX that minimizes the potentially serious cardiovascular findings that were observed in the [VIGOR] study, and thus, misrepresents the safety profile for VIOXX. Specifically, your promotional campaign discounts the fact that in the VIGOR study, patients on VIOXX

> were observed to have a four to five fold increase in myocardial infarctions (MIs) compared to patients on the comparator non-steroidal anti-inflammatory drug (NSAID), Naprosyn (naproxen).
>
> Although the exact reason for the increased rate of MIs observed in the VIOXX treatment group is unknown, your promotional campaign selectively presents the following hypothetical explanation for the observed increase in MIs. You assert that VIOXX does not increase the risk of MIs and that the VIGOR finding is consistent with naproxen's ability to block platelet aggregation like aspirin. ***That is a possible explanation***, but you fail to disclose that your explanation is hypothetical, has not been demonstrated by substantial evidence, and that there is another reasonable explanation, that VIOXX may have pro-thrombotic properties.

The DDMAC Letter targeted only an imbalance in some of Merck's promotional efforts; it did not contend that the "naproxen hypothesis" was wrong or that Defendants did not believe it to be true. All of the information in the DDMAC Letter concerning the CV safety of VIOXX was based on the VIGOR results themselves or on information publicly discussed following the release of the VIGOR results and at the February 8, 2001 AAC meeting.

136. The DDMAC Letter received widespread coverage by the media and securities analysts. Nevertheless, securities analysts continued to project that VIOXX would generate blockbuster revenues for Merck. For example, on September 25, 2001, Credit Suisse First Boston issued an analyst report that concluded: "[w]e retain our Buy rating on Merck. . . ." That same day, Lehman Brothers issued a report that maintained its "Strong Buy" recommendation and a $90 price target for Merck. The Lehman report noted that "[w]arning letters of this nature are certainly not unusual and in fact [are] almost a staple of the pharmaceutical industry today. As pointed out in the [DDMAC Letter], DDMAC does not dispute Merck's claims."

137. In an October 9, 2001 *New York Times* article entitled "For Pain Reliever, Questions of Risk Remain Unresolved," defendant Scolnick again falsely reiterated his and Merck's purported belief in the "naproxen hypothesis." Scolnick stated that Merck's position

throughout was that "the likeliest interpretation of the data is that naproxen lowered the thromboembolic event rate," and that Merck had "found no evidence that VIOXX increased the risk of heart attacks." Scolnick added that without the theoretical questions raised by Dr. FitzGerald (based on the results of Protocol 023), "no one would have a question remaining in their mind that there might be an additional interpretation."

F. Merck Wrongfully Changes Causes of Death in Its ADVANTAGE Trial to Minimize the Risk of "Rais[ing] Concerns" About the "Naproxen Hypothesis"

138. Merck's and the Officer Defendants' claims concerning the "naproxen hypothesis" were further undermined when Merck and the Officer Defendants learned the results of another trial, known as ADVANTAGE, which concluded just days after Merck had issued its first materially false and misleading press release concerning the VIGOR CV results.[8]

139. ADVANTAGE was a so-called "seeding" trial undertaken at the behest of Merck's marketing division (rather than Merck's medical research division). The term "seeding trial" refers to a pharmaceutical study whose purpose is not to further medical knowledge of the drug but rather to introduce it to a large number of doctors and to compensate them for their participation in the trial in the hope that they will continue to prescribe that drug in the future.

140. The purported goal of the ADVANTAGE seeding trial was to demonstrate that VIOXX was less likely to pose GI problems than naproxen -- which had also been the goal of the VIGOR study. Compared to VIGOR, ADVANTAGE was shorter in duration (three months), involved a lower dosage of VIOXX (only 25 mg compared to 50 mg in VIGOR), and had fewer patients (5,557 as compared to VIGOR's 8,076).

[8] ADVANTAGE is an acronym for "Assessment of Differences Between VIOXX and Naproxen to Ascertain Gastrointestinal Tolerability and Effectiveness."

141. ADVANTAGE had one key difference from VIGOR, however. Although the Merck scientists who had designed VIGOR had intentionally tried to exclude from the trial all patients who took low dose aspirin to prevent cardiovascular problems in order to eliminate the patients who were most likely to be vulnerable to VIOXX's prothrombotic properties (and thereby to minimize the number of heart attacks and strokes reported in that trial), the marketing executives who designed ADVANTAGE did ***not*** require the physicians who administered the trial to exclude patients taking low dose aspirin. Accordingly, in contrast to the VIGOR study population, approximately 13% of the patients in each treatment group in ADVANTAGE were taking low dose aspirin. Because a larger percentage of higher-risk patients participated in ADVANTAGE, it was more likely that adverse CV events would be observed in ADVANTAGE and that ADVANTAGE's CV results would be even worse, from Merck's point of view, than those in VIGOR.

142. By no later than early April 2000, just one week after Merck released its initial press release concerning VIGOR's results, all ADVANTAGE patients had completed their treatment and the preliminary results of the trial had become available internally at Merck.

143. In an April 3, 2000 email exchange, defendants Reicin and Scolnick, and Merck scientist Dr. Shapiro, discussed the preliminary results of the ADVANTAGE trial. Defendant Reicin noted that there were ***seven*** heart attacks in one treatment group, compared to only ***one*** in the other group. Although the two treatment groups were still "blinded" at that time, there could have been little doubt among Reicin, Scolnick and Shapiro that the first group was the VIOXX group and the second group was the naproxen group.

144. These results triggered an angry internal response from defendant Scolnick. As reported after the Class Period in an April 24, 2005 *New York Times* article entitled "Evidence in

VIOXX Suits Shows Intervention by Merck Officials," Scolnick asserted in an internal email that ADVANTAGE served "no scientific purpose" (because VIOXX had already been tested against naproxen in VIGOR) and that "***Small marketing studies which are intellectually redundant are extremely dangerous***."

145. Senior Merck scientists did more than simply complain about ADVANTAGE, however. Unbeknownst to the public, to make the ADVANTAGE results appear less damaging for VIOXX, Merck scientists ***improperly changed the initially reported causes of patient deaths in the study to "improve" the study's results***. For example, on November 8, 2000, Merck scientist Eliav Barr emailed defendant Reicin concerning the death of a 73 year old woman who had been taking VIOXX in the ADVANTAGE trial. Dr. Barr wrote:

> ***Common things being common, the clinical scenario is likely to be MI [heart attack].*** Certainly it is not definitive. I just used my clinical judgment. ***If it is easier to call this an unknown cause of death, I could be persuaded to say that as well.***

In response, defendant Reicin wrote to Barr: "***I would prefer unknown cause of death so that we don't raise concerns***." In this fashion, Merck "adjudicated" two of the seven heart attacks reported in the preliminary ADVANTAGE results into "sudden/unknown" cardiac events and transformed the study's statistically significant 700% difference in the rate of heart attacks (seven heart attacks in patients taking VIOXX compared to only one taking naproxen) into a 500% difference which -- because of the size of the sample -- was ***not*** statistically significant.

146. Approximately three years later, Merck finally published the purported "results" of ADVANTAGE in the *Annals of Internal Medicine* ("*Annals*") on October 7, 2003. The *Annals* article was principally drafted by Merck scientists. The article published the manipulated cause of death numbers.

147. Merck's improper tampering with the ADVANTAGE results was not revealed until April 24, 2005 in a *New York Times* article, entitled "Evidence in VIOXX Suits Shows Intervention by Merck Officials," which reported:

> In 2000, amid rising concerns that its painkiller VIOXX posed heart risks, Merck overruled one of its own scientists after he suggested that a patient in a clinical trial had probably died of a heart attack. In an email exchange about VIOXX, the company's most important new drug at the time, a senior Merck scientist repeatedly urged the researcher to change his views about the death "so that we don't raise concerns." In reports to the Food and Drug Administration and in a paper published in 2003, Merck listed the cause death as "unknown" for the patient, a 73-year-old woman.

G. 2001: The Undisclosed Results of Merck's Studies of VIOXX In Alzheimer's Disease Patients Show that VIOXX Raises the Risk of Cardiac Mortality

148. Merck also continued to propagate its "naproxen hypothesis" and to tout VIOXX's commercial prospects in the face of the adverse results of two other major VIOXX clinical trials.

149. Specifically, from April 2001 through the end of the Class Period, Merck and the Officer Defendants were privy to the unfavorable results of two clinical trials conducted by Merck to assess the effects of VIOXX on the occurrence and progression of Alzheimer's disease (known as Protocol 078 and Protocol 091). These two studies showed significantly higher mortality rates among patients who took VIOXX, including a sharply higher rate of deaths from heart disease.[9]

150. At the time Merck began Protocols 078 and 091 in 1998, some studies suggested that inflammatory mechanisms were associated with Alzheimer's disease and that the COX-2

[9] Protocols 078 and 091 showed that VIOXX did not have any beneficial impact on the occurrence and progression of Alzheimer's disease. Merck began a third Alzheimer's trial known as Protocol 126, but according to published reports, discontinued it in March 2001 after Protocol 091 showed no benefit.

enzyme might aggravate such inflammation. This led Merck to hypothesize that treatment with a selective COX-2 inhibitor such as VIOXX might retard the development or progression of Alzheimer's disease.

151. Merck designed Protocol 078 to study whether treatment with VIOXX could delay the onset of Alzheimer's disease (the "Prevention Trial"). A total of 1,457 patients over the age of 65 with mild cognitive impairment took part in the Prevention Trial, with 725 receiving VIOXX (only 25 mg, once daily) and 732 patients receiving a placebo. The trial was initially scheduled to last two years.

152. Merck designed Protocol 091 to assess the effect of VIOXX in slowing the progression of dementia in patients with established Alzheimer's disease (the "Treatment Trial"). A total of 692 patients over the age of 50 who met standard research criteria for possible or probable Alzheimer's disease and had mild or moderate dementia participated in the Treatment Trial, with 346 receiving VIOXX (25 mg once daily) and 346 receiving placebo.[10]

153. According to Merck, both the Prevention Trial and the Treatment Trial were conducted on an "intention-to-treat" (also known as an "intent-to-treat") basis. In an intention-to-treat study, data is collected and reported based on the initial treatment intent, and not on the duration of the treatment that is actually administered. Thus, participants in the Prevention and Treatment Trials who discontinued treatment were asked to return to the clinic for all remaining visits and assessments during the full time period that researchers had intended for them to receive treatment (even though they might have already stopped taking the medication).

[10] Of the patients initially assigned to the VIOXX group, thirty-five patients received 25 mg of VIOXX for 15 months, and 311 patients received VIOXX 25 mg only for 12 months and then received a placebo for three months.

Intention-to-treat analysis is considered the "gold standard" in clinical trials because it helps to avoid bias and other errors that can arise due to treatment discontinuation.

154. Merck also planned to perform an "on-treatment" analysis of the Alzheimer's Prevention and Treatment Trials. In an on-treatment analysis, data is reported only through the time period during which patients are actually taking the treatment (or through a short time thereafter). Merck's data analysis plan for the Prevention and Treatment Trials called for data to be reported through fourteen days after patients discontinued the treatment.

155. In April 2001, consistent with its proposed data analysis protocols, Merck conducted internal "intention-to-treat" and "on-treatment" analyses of the results of the Prevention and Treatment Trials. An April 8, 2001 internal Merck memorandum, authored by Joshua Chen, Ph.D., a Merck statistician, entitled "MK-0966 [VIOXX] Combined Mortality Analysis Protocol 091 + Protocol 078," summarized the overall mortality data from the Prevention and Treatment Trials that Merck had collected up to that time.[11] This April 2001 memorandum, which did not become public until after the Class Period, included separate intention-to-treat and on-treatment analyses of the Prevention and Treatment Trials and analyses of the two trials combined.[12]

156. ***All three of the intention-to-treat analyses prepared in April 2001 found a statistically significant increased risk of mortality in patients taking VIOXX compared to patients taking placebo.*** The intention-to-treat analysis for the Prevention Trial data available up to that point showed that there were twenty-one deaths in patients treated with VIOXX compared

[11] As of April 2001, the Treatment Trial had been completed and the Prevention Trial was still in progress. The cut-off date used for the Prevention Trial data was March 23, 2001.

[12] For the intention-to-treat analysis, the memorandum included events occurring during the study period of Protocol 091 plus 14 days and the last follow-up for patients in Protocol 078 plus 14 days. For the on-treatment analysis, the memorandum included events which occurred during treatment with the drug or within 14 days after discontinuation of the study drug.

to only nine deaths in patients treated with placebo -- ***a statistically significant 257% increase in the risk of death among VIOXX patients in the Prevention Trial***. The intention-to-treat analysis for the Treatment Trial showed that there were thirteen deaths in patients treated with VIOXX compared to only three deaths in patients treated with placebo -- ***a statistically significant 467% percent increase in the risk of death among VIOXX patients in the Treatment Trial***. Merck's internal aggregated intention-to-treat analysis, which combined both the Prevention and Treatment Trials, further showed that VIOXX was associated with a ***statistically significant 287% increase in total mortality in VIOXX patients in the aggregated Prevention and Treatment Trials*** (thirty-four deaths in patients treated with VIOXX compared to only twelve deaths in patients treated with placebo.) These statistically significant differences in mortality would plainly have been considered material by analysts and investors had they been disclosed to the market.

157. ***The on-treatment analyses of the Treatment Trial, and of the combined Prevention and Treatment Trial data, also found statistically significant increased risks of mortality in patients taking VIOXX***. On an "on treatment" basis, in the Prevention Trial there were thirteen deaths in patients treated with VIOXX compared to only seven deaths in patients treated with placebo, resulting in a highly elevated 217% increase in the risk of death among VIOXX patients that fell slightly short of being statistically significant. However, notwithstanding the relatively small sample size, the on-treatment analysis for the Treatment Trial showed that there were nine deaths in patients treated with VIOXX compared to only two deaths in patients treated with placebo -- ***a statistically significant 500% increase in the risk of death among patients who took VIOXX***. Merck's internal aggregated on-treatment analysis, combining both the Prevention and Treatment Trials, showed that VIOXX was associated with ***a***

statistically significant 283% increase in total mortality in VIOXX patients in the combined Prevention and Treatment Trials (twenty-two deaths in patients treated with VIOXX compared to only nine deaths in patients treated with placebo.)

158. Also unbeknownst to the public, these statistically significant increased risks of mortality in patients taking VIOXX were fueled in large part by statistically significant increased risks of heart disease deaths among patients taking VIOXX. In April 2008, Dr. Bruce Psaty, a Professor of Medicine and Epidemiology and a member of the Cardiovascular Health Research Unit at the University of Washington School of Medicine, and Richard A. Kronmal, Ph.D., a Professor of Statistics and Biostatistics at the University of Washington School of Public Health and Community Medicine who served as an expert for plaintiffs in VIOXX product liability litigation and thus had access to previously-undisclosed materials, published their own independently prepared mortality analysis of Merck's internal Prevention and Treatment Trial data files in an article in *JAMA* entitled "Reporting Mortality Findings in Trials of Rofecoxib for Alzheimer Disease or Cognitive Impairment." In that article, Dr. Kronmal revealed that there were approximately ***3.5 times*** more heart disease-related deaths in the Prevention and Treatment Trials among patients taking VIOXX than among those taking placebo, and that the difference was statistically significant.[13]

159. Although this adverse information was plainly in Merck's and the Officer Defendants' possession throughout the Class Period, these Defendants continued to tout the "naproxen hypothesis" and VIOXX's commercial prospects without disclosing any of this statistically significant adverse Alzheimer's trial data to the public. Indeed, it appears that these

[13] Dr. Kronmal classified the causes of death in those studies based on data presented in the July 2001 SUR that Merck had submitted to the FDA for the Treatment Trial, and in the Clinical Study Report that Merck filed with the FDA in July 2003 for the Prevention Trial.

Defendants also failed to disclose accurate and complete data for the Alzheimer's studies to the FDA. For example, in July 2001, Merck filed a Safety Update Report ("SUR") with the FDA that misrepresented its April 2001 mortality findings from the Prevention and Treatment Trials by failing to provide the FDA with either its intention-to-treat data (which would have shown statistically significant increased mortality rates in the Prevention and Treatment Trials separately, as well as on a combined basis) or its on-treatment data (which would have shown statistically significant increased mortality rates in the Treatment Trial and the aggregated Prevention and Treatment Trial data). Instead, Merck improperly (and retrospectively) concocted a new definition for "mortality events" for the data it presented to the FDA in its SUR. Utilizing this specially crafted definition for mortality events -- dubbed by Merck "On Drug – SUR" -- Merck reported to the FDA substantially reduced, and non-statistically significant, increased risks of mortality in the Prevention and Treatment Trials.

160. As described in an October 31, 2001 internal Merck memorandum from Raymond Bain, Merck's Vice-President for Biostatistics and Research Decision Sciences, to Drs. Nies and Gertz, Merck's post hoc "On Drug – SUR" definition included not only deaths that occurred during the period that the patient was taking treatment (either VIOXX or placebo) or through fourteen days after discontinuation, but also deaths that happened after that period so long as Merck determined that the death was "linked" to an event that happened while the patient was taking the drug or in the fourteen days after the patient discontinued treatment. This October 2001 internal Merck memorandum shows that Merck did not begin to employ this mortality event definition until the time approached when Merck had to provide data on the Alzheimer's Prevention and Treatment Trials to the FDA.

161. Utilizing this new "mortality event" definition, Merck told the FDA in July 2001 that fifteen patients taking VIOXX had died in the Prevention Trial as compared to nine patients taking a placebo -- a ***non***-statistically significant 187% increase in the risks of death among VIOXX users. Merck also told the FDA that fourteen patients taking VIOXX had died in the Treatment Trial as compared to eight patients taking placebo -- a ***non***-statistically significant 209% increase in the risk of death among VIOXX users. On the basis of these numbers, Merck made the materially false and misleading representation to the FDA that "review of the deaths does not identify a specific increased risk with rofecoxib," and that "the profile of serious clinical adverse experiences with rofecoxib is generally similar to that of placebo in a large cohort of patients, most of whom were older than 65 years of age." Merck's misrepresentations misled the FDA regarding the magnitude and significance of the VIOXX mortality risk, and were part of Merck's and the Officer Defendants' fraudulent effort to keep the truth about VIOXX's safety concealed from investors.

162. Although Merck had materially misrepresented the rates of deaths among patients using VIOXX in the Alzheimer's disease trials in its submissions to the FDA, the FDA still privately expressed concern about the number of deaths observed in the Treatment Trial. On December 5, 2001, the FDA sent a non-public letter to Merck asking whether the Prevention Trial, which was still ongoing, should continue based on the reported excess mortality (which Merck had understated) observed in the Treatment Trial: "Please clarify whether the safety monitoring board and the IRB [institutional review board] overseeing these studies are aware of the excess in total cause mortality in the Vioxx 25 mg group as compared to placebo (p=0.026) and the trend against Vioxx 25 mg on CV mortality compared to placebo. . . . ***Have these oversight groups commented on the ethics of continuing study 078 in light of the mortality***

data?" The FDA's letter to Merck assumed that Merck had DSMBs in place for the Prevention and Treatment Trials, but in fact those trials did ***not*** have DSMBs in place. Merck had avoided the independent oversight and monitoring that a DSMB provides by simply not creating DSMBs for its Alzheimer's disease trials. Instead, the only human-subject protections available to the study participants were those provided by (i) the investigators, who were blinded both to the treatment allocation (*i.e.*, blinded as to whether a patient was in the VIOXX arm or the placebo arm) and to the findings for study-wide adverse events, and (ii) the Merck reviewers, who were obviously conflicted and ultimately chose to ignore and misrepresent serious safety issues.

163. The planned duration of the Prevention Trial was two years, but in 2002, instead of discontinuing the Prevention Trial, Merck extended it beyond its original cut-off date even though the data indicated that Alzheimer's disease was progressing more rapidly in the patients taking VIOXX than in those taking placebo and that there was a statistically-significant increased risk of death in Alzheimer's study participants who took VIOXX. However, Merck failed to disclose those facts to the public, to the Institutional Review Boards ("IRBs") overseeing the trials, or to study participants themselves -- even as Merck was asking those cognitively impaired study participants to give their consent to continue to participate in the Prevention Trial for an additional two years.

164. In the words of the two authors of the post-class period April 2008 *JAMA* article discussing Merck's conduct with respect to the Alzheimer's disease studies, the mortality findings and the Alzheimer's disease findings known to Merck in 2002 "would, in [our] judgment, have prompted a DSMB, if it had existed, to stop the trial early." But a decision to stop an ongoing Merck study due to VIOXX's increased mortality risk would have been a

devastating blow to Merck at a time when it was committed, for compelling financial reasons, to continue to falsely reassure the market that VIOXX was safe. So Merck continued the study.

165. Merck's and the Officer Defendants' decisions to conceal the truth and extend the Prevention Trial unfortunately took a predictable human toll on participants in the study. Indeed, during the additional duration of the Prevention Trial, there were approximately eight excess deaths among those randomly assigned to receive VIOXX (twenty additional deaths among those assigned to VIOXX compared to only twelve among those assigned to placebo). In the words of the authors of the April 2008 *JAMA* article: "[The] failure of [Merck] to inform IRBs of a safety issue violate[d] the trust of those human participants who volunteered to advance science, medicine, and public health."

166. Merck never publicly revealed the adverse facts concerning the Alzheimer's studies during the Class Period. Their disclosure would have severely jeopardized VIOXX's commercial viability and the financial health of Merck as a whole.

H. Defendants Successfully Keep Merck's Internal Conclusions About the True Significance of the VIGOR Results off VIOXX's Label

167. According to a May 5, 2005 memorandum (the "Congressional Memorandum") issued after the Class Period by the minority members of the United States House of Representatives Government Reform Committee (the "House Government Reform Committee"), there was a two-year delay between the time that Merck filed a request (on June 29, 2000) to change the initial VIOXX label to reflect the purported beneficial GI findings in the VIGOR Study and the time that the initial VIOXX label was changed to "include cardiovascular data from VIGOR." According to the Congressional Memorandum, which was based on non-public documents obtained or subpoenaed by Congress after the Class Period:

> The extended delay resulted, in part, from FDA's need to convene an advisory committee meeting and conduct extra analyses**.** It also

> was due to a series of disputes between the agency and the company. Under the Food, Drug and Cosmetic Act, FDA and manufacturers must agree on label changes. For approximately six months, Merck resisted a variety of FDA's proposals, leading to an extended series of conference calls to negotiate differences.

168. The Congressional Memorandum further reported that the "FDA initially requested [in a non-public communication] that the label warn physicians that VIOXX could cause heart attacks and other cardiovascular problems." To that end, the FDA proposed that the VIOXX label include the following information in the "Warning" section:[14]

> ***Vioxx should be used with caution in patients at risk of developing cardiovascular thrombotic events such as those with a history of myocardial infarction and angina and in patients with pre-existent hypertension and congestive heart failure.***
>
> ***The risk of developing myocardial infarction in the VIGOR study was five fold higher in patients treated with Vioxx 50 mg (0.5%) as compared to patients treated with naproxen (0.1%)***….This finding was consistent with a smaller and shorter study using Vioxx 25 mg that allowed the use of low dose ASA [aspirin.] Prospective, well powered, long-term studies required to compare the incidence of serious CV events in patients taking Vioxx versus NSAID comparators other than naproxen have not been performed.

169. According to the Congressional Memorandum, the FDA's proposed warning "***was unacceptable to Merck.***" In fact, although Merck believed that VIOXX was prothrombotic, the Officer Defendants recognized that such a warning would have a material adverse impact on

[14] FDA regulations require that information concerning risks associated with a drug be set forth on the label according to the seriousness of the risk. For example, the "Contraindications" heading (the most serious of the "headings") would indicate "situations in which the drug should not be used because the risk of use clearly outweighs any possible benefit." 21 C.F.R. § 201.57(d) (v)(d)(j)). The "Warning" section would indicate that there is reasonable evidence of an association of a serious hazard [or risk] with a drug; a causal relationship need not have been proved. 21 C.F.R. § 201.57(3) (v)(e). The "Precautions" section merely reflects "information regarding any special care to be exercised by the practitioner for safe and effective use of the drug." 21 C.F.R. § 201.57(3)(v)(f).

VIOXX sales and thus refused to agree to the FDA's proposed language, in form or substance, in the "Warnings" section of any of VIOXX's drug labels during the Class Period.

170. Indeed, as discussed below, even when the VIOXX label was changed in April 2002 to reflect the VIGOR results (including the favorable GI findings), Merck only agreed to inclusion of the adverse CV results from VIGOR in the "Precautions" section of the label. In addition, the April 2002 VIOXX label included watered-down language to the effect that "the significance of the cardiovascular findings of these three studies (VIGOR and 2 placebo-controlled studies) is unknown."

171. In an April 2002 conference call with analysts and investors addressing the labeling changes for VIOXX, Merck spokesperson Mark Stejbach falsely reiterated that it was Merck's "belief that the [CV] effect seen in VIGOR were the results of the anti-platelet effect of naproxen," and added that "I think that's a position Merck has always had and now its quite clearly laid out in the labeling."

I. 2003-2004: Merck Continues To Vigorously Defend VIOXX's Safety

1. October 2003: Merck Disparages the Brigham Study Findings, and Again Reassures the Public That VIOXX Is Safe

172. In September 2003, abstracts of papers to be presented at an upcoming meeting of the American College of Rheumatology began to circulate. An abstract for one of these papers, entitled "The Relationship Between COX-2 Inhibitors and Acute Myocardial Infarction," reported that in a "matched case-control study of 54,475 patients ≥ 65 years of age," "current rofecoxib [VIOXX] use was associated with an increased adjusted relative risk of acute myocardial infarction [heart attack] compared with celecoxib [Celebrex] use and with no NSAID use [placebo]." In other words, the abstract reported that a large epidemiological study

(supported by Brigham and Women's Hospital in Boston (the "Brigham Study")) had found that VIOXX was associated with a greater risk of heart attack than either Celebrex or placebo.

173. As early as September 17, 2003, an internal Merck document shows that Merck was briefing its sales force concerning ways to mitigate the effect of this study on VIOXX sales. Nonetheless, as later reported by *Reuters News Service* on October 22, 2003, word of the Brigham Study led to a decline in sales of VIOXX in the third quarter of 2003. As the article, entitled "Merck to Cut 4,400 Jobs, Posts Flat Earnings," stated:

> Merck & Co. Inc. said on Wednesday it would cut 4,400 jobs and reported disappointing earnings, hurt by falling sales of arthritis medicine VIOXX and a paucity of profitable new drugs. . . .Sales of VIOXX fell 32 percent in the period to $510 million. ***The arthritis drug is suffering from clinical trial data suggesting it might slightly raise the risk of heart attacks***, and the growing perception that its pain-fighting capabilities are no better than traditional painkillers.

174. On October 28, 2003, the results of the Brigham Study were formally presented at the annual meeting of the American College of Rheumatology. Two days later, on October 30, 2003, *The Wall Street Journal* published an article, entitled "VIOXX Study Sees Heart-Attack Risk," which revealed the results of the Brigham Study to the broader public. The article stated:

> Brigham & Women's Hospital rheumatologist and epidemiologist Daniel H. Solomon headed the study, which looked at records of 54,475 Medicare patients, all of them over 65.
>
> Researchers found that the apparent cardiac risk was greatest in the first 90 days in which a patient is taking VIOXX, which generically is known as rofecoxib. ***In the first 30 days, the researchers found, VIOXX was linked to a 39% increased heart-attack risk compared with Celebrex. Between 30 and 90 days, that increased relative risk was 37%***.
>
> * * *
>
> Eric J. Topol, chairman of cardiovascular medicine at the Cleveland Clinic and one of the authors who first raised the issue two years ago, called the research "the best study to date."

* * *

> The new study, Dr. Topol said, "greatly substantiates our concerns about the cardiac side effects." He observed that the possible cardiac effects of VIOXX appear "worse with the higher doses."

175. Merck immediately moved to counter the data generated by the Brigham Study and to discount the study's conclusions. For example, in the October 30 *Wall Street Journal* article and again in an article published in *American Health Line* on October 31, 2003, defendant Reicin publicly disparaged the study, stating that: "Randomized clinical trials are the gold standard and this isn't such a trial...In our placebo-controlled randomized trials, we have found no significant difference between Vioxx and placebo." Defendant Reicin's falsely reassuring statements helped prevent Merck's stock from experiencing any significant decline in response to the public release of the Brigham Study findings.

176. On May 4, 2004, the Brigham Study was published in the American Heart Association journal *Circulation*, reiterating the results that were first made public in October 2003.

177. However, not only did Merck publicly disparage and attempt to discredit the results of the Brigham Study, but according to a May 18, 2004 *Wall Street Journal* article, entitled "Merck Takes Author's Name Off VIOXX Study," Merck had ordered the name of one of its epidemiologists removed from the list of authors of the Brigham Study in an effort to distance itself from the Study's adverse findings concerning VIOXX's safety profile:

> Stepping into thorny ethical territory, drug titan Merck & Co. ordered the name of one of its epidemiologists purged from the list of authors on a research paper -- after the study produced an unflattering portrait of a blockbuster drug Merck happens to make.
>
> * * *
>
> "It's an enormous disservice to the reader," says Drummond Rennie, deputy editor of the Journal of the American Medical

> Association. "If the people up there in the list of authors aren't responsible for everything in the article, something's wrong. ***It's completely unethical.***"
>
> * * *
>
> "Merck disagreed with the conclusions and didn't think it was appropriate to have a Merck author," company spokeswoman Mary Elizabeth Blake said.
>
> * * *
>
> The eighth [author] was Carolyn C. Cannuscio, a Merck epidemiologist.
>
> When the article appeared, its conclusion -- that Vioxx "was associated with an elevated relative risk of acute myocardial infarction [heart attack]" -- was the same as before. So was the methodology. But this time, Dr. Cannuscio's name was missing.
>
> * * *
>
> ***For Merck, maintaining Vioxx sales is essential***. With $2.55 billion in 2003 sales, it is among Merck's top drugs. The company is under considerable pressure these days, with some promising experimental drugs having failed and the cholesterol drug Zocor facing patent expiration in 2006.
>
> * * *
>
> JAMA editor Catherine DeAngelis is disappointed that Merck didn't see this as a chance to show that sponsors of research can willingly publish findings that run contrary to their own interests. ***"They missed a wonderful opportunity to get some good publicity for the pharmaceutical industry," she says. "Aren't they seeking truth?"***

178. Merck and the Officer Defendants were not, in fact, seeking the truth. As alleged herein, Merck and the Officer Defendants consistently misrepresented and concealed their actual beliefs concerning the safety of VIOXX and the totality of the information that caused them to have that belief, and as a result investors continued to be misled as to the enormous risk that disclosure by Merck of VIOXX's true safety profile would jeopardize VIOXX's commercial viability and its ability to generate substantial revenues for the Company. To ensure sales of

VIOXX remained strong, however, the Officer Defendants continued to suppress, obscure, and distort the truth about VIOXX. In an article titled "Coxibs, Science, and the Public Trust," that appeared in the January 24, 2005 edition of *Archives of Internal Medicine*, Daniel Solomon and Jerry Avorn, two of the authors of the Brigham Study, commented on Merck's scheme to conceal the truth about VIOXX: ***"[E]ven after funding and agreeing with the design of the Study, Merck publicly discredited our findings***."

2. August 2004: Merck Disparages the Kaiser Study Findings, and Again Reassures the Public That VIOXX Is Safe

179. On August 25, 2004, *Bloomberg News* reported that a study funded by the FDA, involving almost 1.4 million Kaiser Permanente health care members (the "Kaiser Study"), found that "[t]he difference in heart risk was statistically significant between a recommended dose of VIOXX, 25 mg a day or less, and Celebrex." Specifically, the Kaiser Study, which was led by Dr. David Graham of the FDA, found that patients taking VIOXX had a 50% greater chance of heart attack and sudden cardiac death than patients taking Celebrex. The Kaiser Study also found that VIOXX, at a dose of 25 mg a day, more than tripled the risk of heart attack compared with patients who had not taken any painkiller within the past two months.

180. On August 26, 2004, Merck, through the *Business Wire*, moved immediately to refute and discredit the Kaiser Study so as to allay any investor concerns by announcing:

> ***Merck strongly disagrees with the conclusions of an observational analysis by Graham et al, presented at an international medical meeting this week, which evaluated the rate of cardiovascular events in patients taking COX-2 specific inhibitors VIOXX (rofecoxib) and Celebrex (celecoxib) and in patients taking non-selective NSAIDs.*** This analysis is a retrospective database analysis -- not a clinical trial. Observational analyses have limitations, often conflict with each other, and must be interpreted within the context of data from large, randomized, controlled clinical trials.

181. The August 26, 2004 press release also quoted Merck's then-head of Merck Research Laboratories, Peter Kim, as stating:

> This retrospective analysis is based only on a database review. Observational analyses do not have the rigor of randomized, controlled clinical trials. The robust clinical trial data available support the safety of VIOXX. ***Based on all of the data that are available from our clinical trials, Merck stands behind the efficacy and safety, including cardiovascular safety, of VIOXX . . . . Nothing is more important to Merck than the safety of our medicines***.

VII. THE FULL TRUTH EMERGES

A. The September 2004 Withdrawal of VIOXX

182. On September 30, 2004, just over a month after publicly reaffirming the "safety, including cardiovascular safety" of VIOXX, Merck shocked the market by announcing that, "effective immediately," it was withdrawing VIOXX worldwide. Merck stated that its decision was based on the recommendation of an independent External Safety Monitoring Board (the "ESMB"), which was overseeing the APPROVe trial. According to Merck, the ESMB recommended that the APPROVe trial be halted because of "an increased risk of confirmed cardiovascular events beginning after 18 months of continuous therapy."

183. That same day, Merck also held a conference call for analysts to further discuss the withdrawal. Merck's then-CEO Raymond Gilmartin stated:

> We are taking this action because we believe it serves the interests of patients . . . We believe it would have been possible to continue to market VIOXX with labeling that would incorporate these new data. However, given the availability of alternative therapies and the questions raised by the data, we concluded that a voluntary withdrawal is the responsible course to take.

184. Securities analysts and market professionals were plainly stunned by the news of VIOXX's withdrawal. For example, the next day, on October 1:

(a) Cummins Catherwood, who helps manage $900 million at Walnut Assets Management in Philadelphia, commented in a *Bloomberg News* article entitled "Merck To Withdraw VIOXX Because of Heart Risks": "***This is just like an avalanche coming out of nowhere***."

(b) A Morgan Stanley report stated: "Yesterday, MRK announced the ***surprise withdrawal*** of Vioxx."

(c) A Cathy Financial report stated: "In a surprising move, Merck announced that it is voluntarily withdrawing its COX-II inhibitor VIOXX from worldwide markets. . . . ***This announcement came as a shock and is a major blow to Merck's already weak business fundamentals*** reflected by Zocor's expected patent expire in mid-2006 and its limited pipeline."

(d) A Bear Stearns report stated: "***Stunningly, Merck withdraws VIOXX from worldwide markets*** due to new colorectal study which unexpectedly showed Vioxx has twice the cardiovascular risk versus placebo after 18 months of continuous use."

185. In response to the September 30 disclosures, the price of Merck securities plummeted, as Merck's shares fell almost 27%, or more than $12 per share, to close at $33 per share. The decline was the greatest one-day percentage price decline of Merck stock since January 1990. The reported trading volume was 145,048,600 shares, more than 426% greater than the next highest reported trading volume since January 1990. The $0.50 to $0.60 decrease in earnings per share that Merck announced on September 30, 2004, represented the loss of at least $1.1 billion in annual earnings. The one day decline wiped out a staggering ***$27 billion*** of the total market capitalization of the Company. Merck was by far the worst performing stock on September 30 in the three stock indexes of which it is a member, the Dow Jones 30 Industrial Average, the S&P 500 Index, and the S&P Pharmaceuticals Index.

VIII. POST-CLASS PERIOD EVENTS

186. In the wake of Merck's September 30, 2004 withdrawal of VIOXX from the market, additional details of Merck's wrongdoing and fraudulent scheme have become public, including but not limited to:

a. The October 6, 2004 *Wall Street Journal* article, which reported that a study led by a Food and Drug Administration safety official found that people taking a high dose of Vioxx were 3.69 times as likely to have a serious cardiac event as people taking Celebrex, while the ratio for people taking a low dose of Vioxx was 1.5. The study projected that the widespread use of Vioxx may have led to more than 27,000 heart attacks and sudden cardiac deaths before the drug's withdrawal;

b. The November 1, 2004 *Wall Street Journal* article, entitled "Warning Signs: E-mails Suggest Merck Knew Vioxx's Dangers at Early Stage," which: (1) revealed internal Company e-mails and other documents that confirmed Merck and the Officer Defendants' awareness of the seriousness of the safety issues affecting VIOXX from prior to the beginning of the Class Period, including Merck scientist Dr. Morrison's February 1997 email expressing concern that the large scale GI outcomes trial would "kill the drug," Defendant Reicin's response proposing to design the large scale GI outcomes trial to preclude patients with a high risk of cardiovascular problems so that the difference in the rate of heart attacks between VIOXX patients and others "would not be evident," and defendant Scolnick's March 9, 2000 email stating the incidence of CV events seen in the VIGOR study was "mechanism-based as we worried it was"; (2) revealed the tactics that Merck had instructed its salespersons to use to "dodge" questions from physicians about VIOXX's cardiovascular safety; and (3) highlighted how Merck and the Officer

Defendants "also went on the offensive against academic researchers who began to question VIOXX's safety";

c. The November 1, 2004 Fortune magazine cover story on VIOXX, entitled "Will Merck Survive VIOXX?; Looming Lawsuits, Angry Investors, Declining Profits: The Vioxx Debacle Is Just The Latest Setback For The Proud Pharmaceutical Giant," which revealed that Merck spent more than $500 million on commercials for Vioxx, but generated roughly $2.5 billion in annual sales at the time of the withdrawal;

d. Dr. Gurkipal Singh's November 18, 2004 revelation in testimony before the Senate Finance Committee that Merck had performed an internal analysis in February 1998 that showed that women in the VIOXX trials had a statistically significant 216% increased risk of suffering an adverse cardiovascular event than patients in other Merck trials taking a placebo (as discussed in ¶ 89);

e. The *New York Times'* April 24, 2005 revelations that defendant Reicin had improperly caused a Merck scientist to change the cause of death of a patient who had been taking VIOXX in the ADVANTAGE trial so as not to "raise concerns," and that the "lead author" of the published ADVANTAGE study had actually not written the ADVANTAGE report and had been unaware of defendant Reicin's misconduct (as discussed in ¶¶ 145-147, 274);

f. National Public Radio's *All Things Considered* June 8, 2006 program, which revealed that half the members of VIGOR's DSMB had substantial conflicts of interest (as discussed in ¶ 101);

g. The November 9, 2007 announcement that Merck had agreed to pay ***$4.85 billion*** to settle state and federal myocardial infarction (heart attack) and ischemic stroke claims filed against the Company in the United States. Notably, unlike Merck's Class Period SEC filings, which characterized the smattering of VIOXX product cases filed during the Class Period as being "normal to its business" and "completely without merit," such language was conspicuously absent from Merck's post-Class Period SEC filings that described the tens-of-thousands of actions commenced after the Company withdrew VIOXX and after information concerning Defendants' wrongdoing was revealed to the market;

h. Dr. Psaty's and Dr. Kronmal's April 2008 article in the *Journal of the American Medical Association* ("*JAMA*"), which revealed Merck's misconduct in concealing statistically significant mortality data in the Alzheimer's Trials from the FDA and publishing false and misleading statements to the public indicating that its data showed that VIOXX was "generally well tolerated" (as discussed in ¶ 158);[15] and

i. On November 22, 2011, it was announced that Merck would pay $950 million and a unit of the company would plead guilty to a criminal misdemeanor charge (for one count of misbranding VIOXX) to resolve a U.S. probe of its illegal marketing of VIOXX. In connection with the settlement, the company paid a $321.6 million criminal fine and $628.3 million to resolve civil claims that it sold VIOXX for unapproved uses and made false statements about its cardiovascular safety.

[15] The internal Merck documents and emails referenced herein have become publicly available, largely as a result of governmental investigations of Merck's conduct and private litigation.

IX. MATERIALLY FALSE AND MISLEADING STATEMENTS

187. As described in detail above and summarized below, Merck's and the Officer Defendants' statements of belief in VIOXX's purported safety and the "naproxen hypothesis" were materially false and misleading because, unbeknownst to investors, such statements were made in bad faith, and misrepresented and/or concealed that Merck and its senior scientists actually believed that VIOXX was prothrombotic (and that it was VIOXX's prothrombotic "mechanism based" characteristics, and not the "naproxen hypothesis," that was the likeliest explanation for VIGOR's CV results). The paragraphs set forth below: (i) identify each of Merck's and the Officer Defendants' Class Period statements alleged to be materially false and misleading under Section 10(b) of the Exchange Act; (ii) set forth when, where, and by whom they were made, and (iii) summarize how and why they were materially false and misleading.

A. Materially False and Misleading Statements Made In Connection With VIOXX's Introduction to the Market

188. On May 21, 1999, the first day of the Class Period, Merck issued a press release which announced that VIOXX "has received marketing approval from the U.S. Food and Drug Administration," and that "VIOXX has been approved for the relief of osteoarthritis (OA), management of acute pain in adults, and treatment of menstrual pain (primary dysmenorrheal)." With respect to VIOXX's side effects, the press release represented that: "The most common side effects reported in clinical trials with VIOXX were upper respiratory infection, diarrhea and nausea."

189. By having chosen to speak about VIOXX's "side effects," Merck had a duty to speak fully and truthfully on that subject. However, in violation of that duty, the above-referenced statements from the May 21, 1999 Merck press release were materially false and misleading because they failed to disclose the "great concern" on the part of Merck and the

Officer Defendants that VIOXX was prothrombotic, and the totality of the facts on which that "great concern" was based, including, *inter alia*, (a) their awareness of the initial manuscripts of the results of Protocol 023, in which Drs. FitzGerald and Catella-Lawson had expressed their view that the results "implie[d] a *major role* for Cox-2 in *systemic* biosynthesis of prostacyclin in humans" and thus upset the natural balance between prostacyclin and thromboxane in the body; (b) their private conversations with preeminent medical researcher Dr. Oates, who supported Drs. FitzGerald and Catella-Lawson's views of the Protocol 023 data; and (c) Merck's internal February 1998 analysis, which showed that female patients in the VIOXX trials had at least a statistically significant 216% increase in the risk of suffering an adverse cardiovascular event compared to patients taking a placebo and that male patients taking had a 28% increase in the risk of such an event. As a result, investors were materially misled as to the enormous risk that VIOXX's true safety profile would jeopardize (or at least significantly limit) VIOXX's commercial viability and ability to generate substantial revenue for the Company.

B. Materially False and Misleading Statements Made During the Second Half of 1999

190. On October 25, 1999, Merck issued a press release announcing the results of a new study that showed that osteoarthritis patients taking VIOXX "developed significantly fewer endoscopic ulcers than patients taking ibuprofen, a commonly used arthritis medicine." The press release also stated that "[i]n other studies, the most common side effects reported in clinical trials with VIOXX were upper respiratory infection, diarrhea, nausea and high blood pressure."

191. By having chosen to speak about VIOXX's "side effects," Merck had a duty to speak fully and truthfully on that subject. However, in violation of that duty, the above-referenced statements from the October 25, 1999 Merck press release were materially false and misleading because they failed to disclose the "great concern" on the part of Merck and the

Officer Defendants that VIOXX was prothrombotic, and the totality of the facts on which that "great concern" was based, including, *inter alia*, the information referenced in ¶ 189 above. As a result, investors were materially misled as to the enormous risk that VIOXX's safety profile would jeopardize (or at least significantly limit) VIOXX's commercial viability and ability to generate substantial revenue for the Company.

192. On November 23, 1999, Merck issued a press release announcing the results of a study published in *JAMA*, which found that VIOXX "significantly reduced the risk of gastrointestinal (GI) side effects" compared to other commonly prescribed NSAIDs. The press release further stated that "[c]ommon side effects reported in clinical trials with VIOXX were upper-respiratory infection, diarrhea, nausea and high blood pressure."

193. The above-referenced statements from the November 23, 1999 Merck press release concerning VIOXX's side effects were materially false and misleading because they failed to disclose the "great concern" on the part of Merck and the Officer Defendants that VIOXX was prothrombotic, and the totality of the facts on which that "great concern" was based, including, *inter alia*, the information referenced in ¶ 189. As a result, investors were materially misled as to the enormous risk that VIOXX's safety profile would jeopardize (or at least significantly limit) VIOXX's commercial viability and ability to generate substantial revenue for the Company.

C. Materially False and Misleading Statements Made in Connection with Defendants' Discussions of Merck's Fourth Quarter and Year-End 1999 Results

194. On March 9, 2000, the VIGOR study results were forwarded to Merck's chief scientist, defendant Scolnick. Later that same day, defendant Scolnick wrote his email to defendant Reicin and other senior Merck scientists who were overseeing Merck's VIOXX's

research programs, in which he acknowledged that the "[adverse] CV events are clearly there" in the VIGOR study results, and that

> It is a shame but it is a low incidence and it is mechanism based as we worried it was. [Dr.] Oates and [senior Merck scientists] Alan [Nies] and Barry [Gertz] were right about the metabolite meanings ie urine Pg [prostacyclin] data…"

(*See* ¶ 110 above).

195. On March 22, 2000 -- just thirteen days after defendant Scolnick's March 9, 2000 email, Merck filed the Company's 1999 Form 10-K with the SEC. Defendant Scolnick signed the 1999 Form 10-K, which stated as follows:

> ***With its product profile for*** strength, ***safety*** and once daily simplicity, ***VIOXX remains the country's fastest growing prescription arthritis medicine***. In the product's first seven months, U.S. physicians wrote more than five million prescriptions. VIOXX is also enjoying success in the 47 other countries in which it has been launched.

196. By having chosen to speak about VIOXX's "profile for …safety" and worldwide commercial success, Merck and Scolnick had a duty to speak fully and truthfully on those subjects. However, in violation of that duty, the above-referenced statements from Merck's 1999 Form 10-K were materially false and misleading because they failed to disclose that Merck and the Officer Defendants actually believed that use of VIOXX caused serious adverse CV events, and the totality of the facts on which their belief was based, including, *inter alia*, (a) their awareness of the initial manuscripts of the results of Protocol 023, in which Drs. FitzGerald and Catella-Lawson had expressed their view that the results "implie[d] a *major role* for Cox-2 in *systemic* biosynthesis of prostacyclin in humans" and thus upset the natural balance between prostacyclin and thromboxane in the body; (b) their private conversations with preeminent medical researcher Dr. Oates, who supported Drs. FitzGerald and Catella-Lawson's views of the Protocol 023 data; (c) Merck's internal February 1998 analysis, which showed that female

patients in the VIOXX trials had at least a statistically significant 216% increase in the risk of suffering an adverse cardiovascular event compared to patients taking a placebo and that male patients taking had a 28% increase in the risk of such an event; and (d) their awareness of non-public data from a study involving more than 164,000 patients -- which Dr. FitzGerald considered to be the "the best comparative clin[incal] data on MI and NSAIDs" -- and which showed that naproxen (like ibuprofen and diclofenac, but unlike aspirin) "had no significant effect" on reducing the risk of suffering a heart attack. As a result, investors remained unaware of Merck's and the Officer Defendants' actual beliefs concerning VIOXX's prothrombotic effects, and were materially misled as to the enormous risk that VIOXX's true safety profile would jeopardize (or at least significantly limit) VIOXX's commercial viability and ability to generate substantial revenue for the Company.

D. Merck and the Officer Defendants' Spring 2000 Statements Announcing the VIGOR Trial Results and Proffering their Purported Belief in the Naproxen Hypothesis

197. On March 27, 2000, Merck issued a press release that purported to summarize the findings of the VIGOR study. The press release emphasized that those who took VIOXX had significantly fewer adverse gastrointestinal events than those who took naproxen in the VIGOR study. Although the press release also acknowledged that those who took VIOXX experienced significantly more thromboembolic events than those who took naproxen in the study, the press release was designed to lead investors and the public to believe that it was the purported cardioprotective effect of naproxen that was the most likely explanation for VIGOR's CV results (the "naproxen hypothesis"), and that VIOXX was not prothrombotic. As the press release stated:

> [S]ignificantly fewer thromboembolic events were observed in patients taking naproxen in this GI outcomes study, which is ***consistent*** with naproxen's ability to block platelet aggregation.

> This effect on these events had not been observed previously in any clinical studies for naproxen. VIOXX, like all COX-2 selective medicines, does not block platelet aggregation and therefore would not be expected to have similar effects.

The press release also stated:

> ***An extensive review of safety data from all other completed and ongoing clinical trials, as well as the post-marketing experience with VIOXX, showed no indication of a difference in the incidence of thromboembolic events between VIOXX, placebo and comparator NSAIDs.*** Further analyses are ongoing, and final results of the GI outcomes study with VIOXX will be presented at peer-reviewed medical meetings this year.

198. However, the statements in Merck's March 27, 2000 press release, which sought to attribute the difference in thromboembolic events in VIGOR to naproxen's purported cardioprotective characteristics (the "naproxen hypothesis"), were materially false and misleading because (a) they constituted an affirmatively false representation that Merck and the Officer Defendants believed in good faith that it was the naproxen hypothesis (rather than VIOXX's prothrombotic effects) that was the most likely explanation of VIGOR's adverse CV results; and (b) failed to disclose that Merck and the Officer Defendants actually believed that use of VIOXX caused serious adverse CV events, and that it was the "mechanism based" effect of VIOXX in suppressing prostacyclin (without suppressing thromboxane) -- rather than the "naproxen hypothesis" -- that explained VIGOR's results, and the totality of the facts on which their belief was based, including, *inter alia*, the information referenced in ¶ 196. As a result, investors were affirmatively misled as to, and remained unaware of, Merck's and the Officer Defendants' actual beliefs concerning VIOXX's prothrombotic effects, and were materially misled as to the enormous risk that VIOXX's true safety profile would jeopardize (or at least significantly limit) VIOXX's commercial viability and ability to generate substantial revenue for the Company.

199. In addition, Merck's further statements in the March 27, 2000 press release to the effect that "[a]n extensive review of safety data from all other completed and ongoing clinical trials**,** as well as the post-marketing experience with VIOXX, showed no indication of a difference in the incidence of thromboembolic events between VIOXX, placebo and comparator NSAIDs" were also materially false and misleading because, at the time the statement was made, Merck and the Officer Defendants were in possession of the results of Merck's non-public internal February 1998 analysis, which showed, *inter alia*, that women taking VIOXX had *at least* a 216% (statistically significant) greater risk of experiencing serious adverse cardiovascular events compared to women not taking any drug in other Merck studies. As a result of these further materially false and misleading statements in the March 27 press release, investors were further materially misled as to the enormous risk that VIOXX's true safety profile would jeopardize (or at least significantly limit) VIOXX's commercial viability and ability to generate substantial revenue for the Company.

200. In the wake of Merck's March 27, 2000 press release, market analysts and members of the press understood that thromboembolic events could be a side effect of VIOXX, but repeated Merck's representations concerning the naproxen hypothesis and statements that there was no evidence from Merck's other clinical data that VIOXX was prothrombotic. For example:

(a) On April 12, 2000, an article in *Biotech Week* entitled "Merck & Co., Inc.: Preliminary Results of Gastrointestinal Outcomes Study Presented" reported that:

> Vioxx, like all COX-2 selective medicines, does not block platelet aggregation and would not be expected to have similar effects. Medicines like aspirin and naproxen that significantly inhibit

> COX-1 block platelet aggregation and therefore have the potential to provide cardioprotection.

and

(b) On April 17, 2000, an analyst report issued by JP Morgan reported that:

> Celebrex showed no statistical difference for NSAIDs on any of a variety of [CV] risk factors. This contrasts to Merck's VIOXX in the VIGOR study, which did show that VIOXX patients experienced more thromboembolic events (*i.e.*, strokes, heart attacks) than NSAID patients. ***This may have been due to the anti-clotting benefits of NSAIDS and the fact that VIGOR did not allow background aspirin therapy***….
>
> While Celebrex showed no disadvantage on thromboembolic events, it narrowly failed to show statistical significance on the primary GI endpoint, while it did demonstrate statistical advantage on a variety of other GI endpoints…. ***For VIOXX, although medical intuition implies that the thromboembolic event issue is an "NSAID-issue," the theoretical [CV] protective benefits of naproxen (the VIGOR comparator NSAID) has not been clinically proven, and the non-aspirin using cut of CLASS did not show the same problem for Celebrex. [However,] In our view, the GI superiority of both Celebrex and VIOXX is the primary issue and should be evident to the FDA.*** We expect meaningful modifications of the standard NSAID GI warning for both products after these data are reviewed.

201. On April 27, 2000 CNBC and *Reuters* reported that some analysts were increasingly concerned that VIGOR's CV data would attract heightened FDA scrutiny. However, in response to what Merck characterized as "speculative news reports," Merck responded with a renewed public relations campaign to emphasize Defendants' purported belief in the "naproxen hypothesis" as the likeliest explanation for the VIGOR results, and to reassure the public that VIOXX was safe. For example, on April 27, 2000, *Reuters* reported that Merck spokesperson Jan Weiner had told *Reuters* "that there was no evidence that VIOXX actually put patients at higher risk of adverse [cardiovascular] events" and that "it was likely that naproxen had conferred protection to patients taking that drug."

202. Similarly, on April 28, 2000, Merck issued a Company press release entitled "Merck Confirms Favorable Cardiovascular Safety Profile of VIOXX," which reaffirmed Merck's purported belief in the "naproxen hypothesis" and reiterated the purported safety profile of VIOXX. As the April 28 press release stated:

> In response to speculative news reports, Merck & Co. today confirmed the ***favorable cardiovascular safety profile of Vioxx***.
>
> In preliminary findings from Merck's large gastrointestinal (GI) study that compared Vioxx in patients with rheumatoid arthritis, significantly fewer heart attacks were observed in patients taking naproxen (0.1 percent) compared to patients taking Vioxx (0.5 percent). ***This result is consistent with naproxen's ability to block platelet aggregation.*** This is the first time this effect of naproxen to reduce these events has been demonstrated in a clinical study. ***Vioxx, like all COX-2 selective medicines, does not block platelet aggregation and therefore would not be expected to have these effects in reducing these events***.
>
> Extensive review of data from the completed osteoarthritis trials and on-going clinical trials with Vioxx, as well as post-marketing experience with Vioxx have shown ***NO DIFFERENCE*** [emphasis in original] in the incidence of cardiovascular events, such as heart attacks, among patients taking Vioxx, other NSAIDs and placebo.

203. The statements in the April 27, 2000 *Reuters* article and Merck's April 28, 2000 press release, which sought to attribute the difference in heart attacks in VIGOR to naproxen's purported cardioprotective characteristics (the "naproxen hypothesis"), were materially false and misleading because (a) they constituted an affirmatively false representation that Merck and the Officer Defendants believed in good faith that it was the "naproxen hypothesis" (rather than VIOXX's prothrombotic effects) that was the most likely explanation of VIGOR's adverse CV results; and (b) failed to disclose that Merck and the Officer Defendants actually believed that use of VIOXX caused serious adverse CV events, and that it was the "mechanism based" effect of VIOXX in suppressing prostacyclin (without suppressing thromboxane) -- rather than the "naproxen hypothesis" -- that explained VIGOR's results, and the totality of the facts on which

their belief was based, including, *inter alia*, the information referenced in ¶ 196. As a result, investors were affirmatively misled as to, and remained unaware of, Merck's and the Officer Defendants' actual beliefs concerning VIOXX's prothrombotic effects, and were further materially misled as to the enormous risk that VIOXX's true safety profile would jeopardize (or at least significantly limit) VIOXX's commercial viability and ability to generate substantial revenue for the Company.

204. In addition, the statements in the April 28, 2000 press release that an "[e]xtensive review of data from the completed osteoarthritis trials and on-going clinical trials with Vioxx, as well as post-marketing experience with Vioxx had shown "no difference" in the incidence of cardiovascular events, such as heart attacks, among patients taking Vioxx, other NSAIDs and placebo" were also materially false and misleading because, at the time the statement was made, Merck and the Officer Defendants were in possession of the results of Merck's non-public internal February 1998 analysis, which showed, *inter alia*, that women taking VIOXX had *at least* a 216% (statistically significant) greater risk of experiencing serious adverse cardiovascular events compared to women not taking any drug in other Merck studies. As a result of these further materially false and misleading statements in the March 27 press release, investors were further materially misled as to the enormous risk that VIOXX's true safety profile would jeopardize (or at least significantly limit) VIOXX's commercial viability and ability to generate substantial revenue for the Company.

205. That the market continued to be misled by Merck's false assurances in April 2000 concerning the safety of VIOXX and the continuing strong commercial prospects and viability of the drug is evidenced by the comments of securities analysts who followed Merck. For example:

(a) On April 28, *Dow Jones*' news wire service reported that perhaps Wall Street's most influential Merck analyst, PaineWebber's Jeff Chaffkin, credited Merck's renewed assurances of VIOXX's "favorable" safety profile. As Dow Jones reported:

> [A]t least one analyst – and the company – said there's ***little to worry about. "This whole thing has been overblown and taken out of context,"*** says Wall Street Journal All-Star analyst Jeff Chaffkin of PaineWebber. "We had this data over four weeks ago. This is nothing new."

(b) On April 28, 2000, Lehman Brothers issued an analyst report which stated:

> Concerns have been ***circulated*** in the press that Merck's Cox-2 inhibitor drug, VIOXX, may be associated with increased risk of stroke or heart attack. These concerns are not supported by the clinical data publicly known. In our March 27 note, we wrote that Merck's preview of the VIGOR study results included a statistically significant differential in thromboembolic events between VIOXX and Naproxen users. Merck attributes the difference to Naproxen's platelet blocking characteristics.

(c) On April 28, 2000, Merrill Lynch issued an analyst report, which stated:

> Detailed data from the [VIGOR] study has not been released. [However,] ***[w]e have no reason to believe Vioxx would cause a greater rate of [CV] events than would be seen without treatment. It may be that Naprosyn [a/k/a naproxen] (which is known to inhibit platelet aggregation and thus blood clot formation) reduces the rate of [CV] events."***
>
> Our estimates and rating [accumulate] are unchanged.

(d) On April 28, 2000, Ryan, Beck, & Co. issued an analyst report that commented, with regard to Merck's reassurances that VIOXX was safe, that "[t]here is no credibility problem for Merck."

(e) On May 1, 2000, Bernstein Research Call issued an analyst report that stated: "We'd be shocked if [the] FDA gave this a second glance, much less re-labeled

VIOXX to suggest greater risks of vascular events. ***It's not VIOXX increasing events, it's Naproxen reducing them."***

(f) On May 2, 2000 Goldman Sachs issued an analyst report that stated:

> VIGOR study of rheumatoid arthritis shows a lower rate of heart attacks among patients receiving naproxen compared to Vioxx users (0.1% for naproxen vs. 0.5% for Vioxx). ***Merck assures that its review of all completed and ongoing studies of Vioxx fails to find any difference in the incidence of [CV] events between Vioxx and other anti-inflammatory drugs (such as naproxen) and placebo.*** We maintain our 2000 sales estimate of $1.7 billion
>
> * * *
>
> This data will be submitted to FDA to support removal of the NSAID class labeling that warns of the potential for [GI] toxicity.
>
> What has attracted more attention is the finding that there were significantly fewer thromboembolic events in the Naproxen group. ***While naproxen is known to inhibit platelet aggregation (or "clumping" that can lead to the formation of clots in arteries), it has never been shown clinically that naproxen prevents heart attacks the way that aspirin, another platelet inhibitor, does. We do not find this lack of data surprising as outcomes studies were never conducted on these older off-patient NSAIDs. It is well known, however, that Cox-2 inhibitors do not inhibit platelet aggregation to any significant degree and would not be expected to prevent heart attacks.***
>
> * * *
>
> If a label change were to be considered by the [FDA], we would not expect either drug, Vioxx or Celebrex, to be given preferential labeling over the other with respect to [CV] safety…***However, we believe the more conclusive GI safety achieved in Merck's VIGOR study could plausibly result in a preferential safety label for Vioxx relative to Celebrex***

206. On May 24, 2000, Merck issued a press release which stated that:

> As previously reported, significantly fewer heart attacks were seen in patients taking naproxen (0.1 percent) compared to the group taking Vioxx (0.4 percent) in this study [VIGOR]. ***The reduction in heart attacks is consistent with naproxen's ability to block platelet aggregation by inhibiting COX-1***. This effect on platelet aggregation is similar to low-dose aspirin, which is used to prevent

> second cardiac events in patients with a history of heart attack, stroke or other cardiac events. Patients taking low-dose aspirin did not participate in VIGOR although 4 percent of patients enrolled in the study did meet the criteria for use of aspirin to prevent second cardiac events. Among the 96 percent of patients in VIGOR who were not candidates for low-dose aspirin for such cardioprotection, there was no significant difference in heart-attack rates – 0.1 percent among patients taking naproxen and 0.2 percent among patients taking Vioxx.

This portion of the press release reiterated the "naproxen hypothesis" and communicated Merck's purported understanding that it was the high-risk, aspirin-indicated 4% of the VIGOR population that was driving the disparity between the VIOXX and naproxen arms of the VIGOR trial. In other words, since the difference in heart attack rates between patients taking VIOXX and naproxen in the remaining 96% of the population was not statistically significant, Merck claimed that the difference in CV events in VIGOR overall was explained by the number of patients that suffered adverse CV events in the 4% subgroup who purportedly should have been taking low-dose aspirin for cardioprotection but did not.

207. Merck's above-quoted statements in the May 24, 2000 press release – which sought to attribute the difference in heart attacks in VIGOR to naproxen's purported cardioprotective characteristics (the "naproxen hypothesis") and stressed a purported difference between the 4% subgroup and the remainder of the VIGOR population – were materially false and misleading because (a) they constituted an affirmatively false representation that Merck believed in good faith that it was the "naproxen hypothesis" (rather than VIOXX's prothrombotic effects) that was the most likely explanation of VIGOR's adverse CV results; (b) failed to disclose that Merck and the Officer Defendants actually believed that use of VIOXX caused serious adverse CV events, and that it was the "mechanism based" effect of VIOXX in suppressing prostacyclin (without suppressing thromboxane) -- rather than the "naproxen hypothesis" -- that explained VIGOR's results, and the totality of the facts on which their belief

was based, including, *inter alia*, the information referenced in ¶ 196; and (c) as explained above, in ¶¶ 123-128, Merck already internally understood that the claim of a difference between the 4% subgroup and the remainder of the VIGOR population was non-existent from a statistical perspective. As a result, investors were affirmatively misled as to, and remained unaware of, Merck's and the Officer Defendants' actual beliefs concerning VIOXX's prothrombotic effects, and were further materially misled as to the enormous risk that VIOXX's true safety profile would jeopardize (or at least significantly limit) VIOXX's commercial viability and ability to generate substantial revenue for the Company.

208. On May 24, 2000, Merck gave a formal presentation of the VIGOR study data at a major digestive disease medical conference. At that conference, Merck again reiterated its "naproxen hypothesis" and touted VIOXX's purported safety. Market analysts again reacted favorably to these further reassurances, while still acknowledging that the "naproxen hypothesis" was not proven. For example:

(a) On May 24, 2000 J.P. Morgan issued an analyst report stating:

> We believe that for both VIOXX and Celebrex, most physicians already believe that the drugs are safer and that the next level of marketing is to take that message directly to consumers…. We continue to be enthusiastic about the COX-2 inhibitors (total class forecast of $13 billion in 2004) ….
>
> …. For both drugs, the safety trials, while ***very impressive***, also present challenges. For VIOXX, there is the increased risk of heart attacks for patients on VIOXX versus naproxen (***probably*** but not conclusively ***due to the anti-platelet effect of naproxen***)….

(b) On May 25, Morgan Stanley Dean Witter issued an analyst report, entitled "Positive Clinical Outcomes Studies Presented at DDW," that stated:

> This week, we attended a number of presentations on the [GI] safety of COX-2 inhibitors at the annual Digestive Disease Week conference. The full data from these clinical outcomes trials have been anticipated since Celebrex and VIOXX were introduced last

> year, because of the potential that the data could lead to a revision of the labels or even removal of the standard NSAID GI warning. Additionally, the partial release of data last month led to some confusion and speculation about the relative safety of the products in the GI and cardiovascular systems.
>
> ***In our opinion, both of these major studies successfully achieved their goals of differentiating the long-term safety profile of the COX-2 inhibitors from those of comparator NSAIDS.*** Though there were some differences in study designs and the results of the CLASS and VIGOR trials, one product does not emerge as clearly superior to the other, in our opinion.

(c) On June 13, 2000, Bernstein Research Call issued a research report, entitled "COX-2 GI Safety Data Will Positively Effect COX-2 Demand; VIOXX Benefits More Than Celebrex, Improving MRK's Near Term Outlook," which stated:

> Our proprietary survey of the arthritis market shows that the pending addition of GI safety data into COX-2 marketing messages will expand demand for the class, contrary to our expectation. We see a near term (6-12 month) gain for the COX-2 class of an additional 5-8% of arthritis category scripts; COX-2's at present have a 38% share.
>
> Merck's VIOXX is the primary beneficiary of this potential inflection point in demand; the 220 physicians surveyed were 20 percent more likely to prefer VIOXX than Celebrex…. Our market simulation changes our mind on VIOXX; we now see the potential for continued growth, and have raised our '00 number by $300M, and our '04 number by $1.1B. VIOXX accounts for one-sixth of our '00 Merck EPS, and almost a fourth of our '04 EPS.
>
> …. Active physicians that saw the VIGOR data including the mention of higher incidence of MI in VIOXX patients not only wrote more COX-2 [prescriptions] than controls for MI-risk only patients, they wrote more VIOXX for these patients than did their control counterparts. GI risk matters more than MI risk in this market, and physicians have apparently taken the view that more VIGOR/VIOXX patients VIGOR/traditional NSAID patients had MI's because no VIGOR patients were allowed aspirin, and traditional NSAIDS block platelet aggregation where COX-2's don't….

> … With VIOXX's outlook improved, our view of the stock improves as well….

209. Merck's statements at the May 24, 2000 digestive disease medical conference, which sought to attribute the difference in heart attacks in VIGOR to naproxen's purported cardioprotective characteristics (the "naproxen hypothesis"), were materially false and misleading because (a) they constituted an affirmatively false representation that Merck and the Officer Defendants believed in good faith that it was the "naproxen hypothesis" (rather than VIOXX's prothrombotic effects) that was the most likely explanation of VIGOR's adverse CV results; and (b) failed to disclose that Merck and the Officer Defendants actually believed that use of VIOXX caused serious adverse CV events, and that it was the "mechanism based" effect of VIOXX in suppressing prostacyclin (without suppressing thromboxane) -- rather than the "naproxen hypothesis" -- that explained VIGOR's results, and the totality of the facts on which their belief was based, including, *inter alia*, the information referenced in ¶ 196. As a result, investors were affirmatively misled as to, and remained unaware of, Merck's and the Officer Defendants' actual beliefs concerning VIOXX's prothrombotic effects, and were further materially misled as to the enormous risk that VIOXX's true safety profile would jeopardize (or at least significantly limit) VIOXX's commercial viability and ability to generate substantial revenue for the Company.

210. Indeed, by vociferously touting VIOXX's purported safety profile during the Class Period, Merck and the Officer Defendants were able to win further acceptance for the "naproxen hypothesis" as the most likely explanation for the VIGOR CV results. For example, on May 25, 2000, Merck marketing executive Margie McGlynn emailed defendants Reicin and Scolnick. The email forwarded two analyst reports "which most clearly demonstrate the success of our efforts to defuse the CV risk issue for VIOXX," and "personally thank[ed them] for all of

[their] efforts and the tremendous support you provided [to] the marketing organization." The analyst reports supported Merck's hypothesis that the difference in rates of heart attacks in VIGOR was consistent with naproxen's ability to block platelet aggregation.

211. On June 29, 2000, Merck issued a press release announcing that Merck "today had submitted a Supplemental New Drug Application for VIOXX" to the FDA seeking to "request labeling changes based on the recently completed 8,000-patient gastrointestinal outcome study called VIGOR." The following day, Merck common stock increased more than $2.50 to close at $76.63 on June 28, compared to its closing price of $74.11 the previous day.

E. Materially False and Misleading Statements Made During the Second Half of 2000

212. On November 23, 2000, the *New England Journal of Medicine* ("*NEJM*") published an article written by several Merck employees, including defendant Reicin and Deborah Shapiro entitled "Comparison of Upper Gastrointestinal Toxicity of Rofecoxib and Naproxen in Patients with Rheumatoid Arthritis." The article formally reported the results of the VIGOR trial, and specifically with respect to myocardial infarctions, reported a relative risk of 0.2. Under General Safety, the article reported that, "[t]he mortality rate was 0.5 percent in the rofecoxib group and 0.4 percent in the naproxen group. ***The rate of death from cardiovascular causes was 0.2 percent in both groups. Ischemic cerebrovascular events occurred in 0.2 percent of the patients in each group***." The article also stated "[t]he rate of myocardial infarction was significantly lower in the naproxen group than in the rofecoxib group (0.1 percent vs. 0.4 percent). ***This difference was primarily accounted for by the high rate of myocardial infarction among the 4 percent of the study population with the highest risk of a myocardial infarction, for whom low dose aspirin is indicated.*** The difference in the rates of myocardial infarction between the rofecoxib and naproxen groups was not significant among the patients

without indications for aspirin therapy as secondary prophylaxis." Finally, the article stated that "[n]aproxen inhibits the production of thromboxane by 95 percent and inhibits platelet aggregation by 88 percent, and this effect is maintained throughout the dosage interval; therefore, the effects of regular use of naproxen may be similar to those of aspirin. . . . Thus, ***our results are consistent with the theory that naproxen has a coronary protective effect and highlight the fact that rofecoxib does not provide this type of protection*** owing to its selective inhibition of cyclooxygenase-2 at its therapeutic dose and higher doses."

213. Merck's presentation of the results of the VIGOR trial relating to the relative risk of VIOXX was entirely geared toward presentation of the "naproxen hypothesis" rather than presenting the alternative explanation for the VIGOR results, that VIOXX was prothrombotic. For example, when reporting data from a clinical trial comparing an active treatment with a comparator treatment, results are typically presented with relative risk representing the risk on the active treatment divided by the risk on the comparator. In VIGOR, this would have resulted in a relative risk of 5 for VIOXX versus naproxen. Instead, Merck presented the risk of the comparator divided by the active treatment, resulting in a relative risk of 0.2 for naproxen versus VIOXX.

214. The remaining portions of the article, which reaffirmed Merck professed belief in the "naproxen hypothesis" and stressed a purported difference between the 4% subgroup and the remainder of the VIGOR population – were also materially false and misleading because (a) they constituted an affirmatively false representation that Merck and the Officer Defendants believed in good faith that it was the "naproxen hypothesis" (rather than VIOXX's prothrombotic effects) that was the most likely explanation of VIGOR's adverse CV results; (b) failed to disclose that Merck and the Officer Defendants actually believed that use of VIOXX caused serious adverse

CV events, and that it was the "mechanism based" effect of VIOXX in suppressing prostacyclin (without suppressing thromboxane) -- rather than the "naproxen hypothesis" -- that explained VIGOR's results, and the totality of the facts on which their belief was based, including, inter alia, the information referenced in ¶ 196; and (c) as explained above, in ¶¶ 123-128, Merck scientists already internally understood that the claim of a difference between the 4% subgroup and the remainder of the VIGOR population was non-existent from a statistical perspective. As a result, investors were affirmatively misled as to, and remained unaware of, Merck's and the Officer Defendants' actual beliefs concerning VIOXX's prothrombotic effects, and were further materially misled as to the enormous risk that VIOXX's true safety profile would jeopardize (or at least significantly limit) VIOXX's commercial viability and ability to generate substantial revenue for the Company.

215. On February 8, 2001, Merck issued a Company press release announcing, among other things, that the FDA Arthritis Advisory Committee had met that day to review Merck's application to modify the prescribing information for VIOXX to reflect results of the VIGOR Study. Commenting on the data that Merck had submitted to the FDA Advisory Committee, Eve Slater, M.D., Merck's Senior Vice President for Clinical and Regulatory Development, stated: "Merck is confident that the data presented today support the excellent safety profile of VIOXX."

216. During the February 8, 2001 public hearing before the FDA Arthritis Advisory Committee ("AAC"), defendant Reicin made the following public statements to the panel: "when you review the results of VIGOR in isolation you don't know whether the imbalance of cardiovascular events [in VIGOR] was caused by a decrease in events on a platelet-inhibiting NSAID, naproxen, or an increase in events on a COX-2 selective inhibitor," *i.e.*, VIOXX.

However, Reicin reiterated that it was Merck's belief that "the decreased cardiovascular events with naproxen in VIGOR is consistent with [naproxen's] potent antiplatelet effects." Defendant Reicin's remarks reassured the members of the AAC; for example, a February 8, 2001 report by *Bloomberg News* quoted Dr. Nigel Harris, the chair of the AAC, as stating "Differences in cardiac risk between VIOXX and naproxen appeared to result from a beneficial effect of naproxen, not a danger from VIOXX." Similarly, defendant Reicin's remarks reinforced what a contemporaneous J.P. Morgan analyst report of February 2, 2001 characterized as "the commonly accepted view that [VIGOR's CV findings are] likely due to the anti-platelet (*i.e.*, anti-clotting) benefits of naproxen (an NSAID) rather than any risk of VIOXX."

217. The statements contained in Merck's February 8, 2001 press release, as well as defendant Reicin's statements reiterating the "naproxen hypothesis" before the FDA Arthritis Advisory Committee, were materially false and misleading because (a) they constituted an affirmatively false representation that Merck and the Officer Defendants believed in good faith that it was the naproxen hypothesis (as opposed to VIOXX's prothrombotic effects) that was the most likely explanation of VIGOR's adverse CV results; and (b) failed to disclose that Merck and the Officer Defendants actually believed that use of VIOXX caused serious adverse CV events, and the totality of the facts on which their belief was based, including, *inter alia*, the information referenced in ¶ 196. As a result, investors remained unaware of Merck's actual beliefs concerning VIOXX's prothrombotic effects, and were materially misled as to the enormous risk that VIOXX's true safety profile would jeopardize (or at least significantly limit) VIOXX's commercial viability and ability to generate substantial revenue for the Company.

218. On April 10, 2001, Merck issued a press release which reported that Merck had received an "approvable letter" from the FDA relating to the Company's application for changes

to the prescribing information for VIOXX, *i.e.*, to include the so-called positive GI findings observed in VIGOR.[16] Merck again expressed its confidence ***"in the comprehensive data that support the excellent gastrointestinal and overall safety profile of VIOXX."***

219. However, the statements in the April 10, 2001 press release concerning Merck's receipt of the approvable letter and VIOXX's safety profile were materially false and misleading because (i) they constituted an affirmatively false representation that Merck and the Officer Defendants believed in good faith that it was the naproxen hypothesis (as opposed to VIOXX's prothrombotic effects) that was the most likely explanation of VIGOR's adverse CV results; and ii) failed to disclose that Merck and the Officer Defendants actually believed that use of VIOXX caused serious adverse CV events, and the totality of the facts on which their belief was based, including, *inter alia*, (a) their awareness of the initial manuscripts of the results of Protocol 023, in which Drs. FitzGerald and Catella-Lawson had expressed their view that the results "implie[d] a *major role* for Cox-2 in *systemic* biosynthesis of prostacyclin in humans" and thus upset the natural balance between prostacyclin and thromboxane in the body; (b) their private conversations with preeminent medical researcher Dr. Oates, who supported Drs. FitzGerald and Catella-Lawson's views of the Protocol 023 data; (c) Merck's internal February 1998 analysis, which showed that female patients in the VIOXX trials had at least a statistically significant 216% increase in the risk of suffering an adverse cardiovascular event compared to patients taking a placebo and that male patients taking had a 28% increase in the risk of such an event; (d) their awareness of non-public data from a study involving more than 164,000 patients -- which Dr. FitzGerald considered to be the "the best comparative clin[incal] data on MI and

[16] An "approvable letter" is defined by the FDA as a written statement that the FDA will approve the application if specific additional information or material is submitted or specific conditions are met. An approvable letter is a first necessary step in the process for obtaining approval of a label change application.

NSAIDs"-- and which showed that naproxen (like ibuprofen and diclofenac, but unlike aspirin) "had no significant effect" on reducing the risk of suffering a heart attack; (e) the non-public final results from Merck's Alzheimer's Treatment Trial (Protocol 091), which showed that VIOXX patients had a statistically significant higher rate of deaths than patients treated by placebo on an ITT basis, on treatment basis, and combined ITT/on treatment basis; (f) the non-public interim results of Merck's Alzheimer's Prevention Trial (Protocol 078), which showed that VIOXX patients had a statistically significant higher rate of deaths than patients being treated by placebo on an "intention to treat" basis and combined ITT/on treatment basis; and (g) the non-public aggregated results of Merck's Alzheimer's trials, which showed that patients taking VIOXX had a statistically significant higher rate of heart disease death. As a result, investors remained unaware of Merck's actual beliefs concerning VIOXX's prothrombotic effects, and were materially misled as to the enormous risk that VIOXX's true safety profile would jeopardize (or at least significantly limit) VIOXX's commercial viability and ability to generate substantial revenue for the Company.

220. On April 11, in response to Merck's April 10, 2001 Company press release, Lehman Brothers issued an analyst report commenting on the approvable letter.

> [I]t is our interpretation from the FDA Advisory committee meeting that we attended this past February and yesterday's receipt of the approvable letter, that Vioxx will achieve an expanded label inclusive of its GI safety over naproxen…. ***While some language may also go into the precaution section of the label regarding the fact that Vioxx (or perhaps COX-2's in general) is not cardioprotective, we expect that the expanded [GI] safety labeling for Vioxx will be the key***. *** Additionally, another major topic of discussion with the panel concerned [CV] risks associated with Vioxx use….While the panel agreed it was unclear what the source of this increased risk associated with Vioxx use was due to, the separation between naproxen and Vioxx was deemed significant enough to be highlighted in some context.****We want to reiterate our belief that this is a strong positive for Vioxx and MRK.***

221. On May 22, 2001, Merck issued a Company press release, which stated, among other things: "In response to news and analyst reports of data the Company first released a year ago, Merck & Co., Inc. today reconfirmed the favorable cardiovascular safety profile of VIOXX."

222. On May 29, 2001, Merck issued another Company press release, which again "reconfirmed the favorable cardiovascular safety profile of VIOXX."

223. However, Merck's statements in the May 22 and 28, 2001 press releases concerning the "favorable cardiovascular safety profile of VIOXX" were materially false and misleading because (a) they constituted an affirmatively false representation that Merck and the Officer Defendants believed in good faith that it was the naproxen hypothesis (as opposed to VIOXX's prothrombotic effects) that was the most likely explanation of VIGOR's adverse CV results; and (b) failed to disclose that Merck and the Officer Defendants actually believed that use of VIOXX caused serious adverse CV events, and the totality of the facts on which their belief was based, including, *inter alia*, the information referenced in ¶ 219. As a result, investors remained unaware of Merck's and the Officer Defendants' actual beliefs concerning VIOXX's prothrombotic effects, and were materially misled as to the enormous risk that VIOXX's true safety profile would jeopardize (or at least significantly limit) VIOXX's commercial viability and ability to generate substantial revenue for the Company.

224. On June 13, 2001, Merck issued a press release announcing, among other things: "In a new meta-analysis combining data from 19 clinical studies with VIOXX (rofecoxib) involving more than 28,000 patients, the relative risks of serious cardiovascular events were similar with VIOXX and placebo, and with VIOXX and the widely prescribed non-steroidal anti-

inflammatory drugs (NSAIDs) ibuprofen, diclofenac and nabumetone." The press release quoted defendant Reicin as stating:

> Results seen in the meta-analysis with VIOXX vs. naproxen are consistent with the ability of naproxen to block platelet aggregation, and, therefore, to act as an anti-platelet agent.

225. However, the statements in the June 13, 2001 press release concerning the "naproxen hypothesis" were materially false and misleading because (a) they constituted an affirmatively false representation that Merck and the Officer Defendants believed in good faith that it was the naproxen hypothesis (as opposed to VIOXX's prothrombotic effects) that was the most likely explanation of VIGOR's adverse CV results; and (b) failed to disclose that Merck and the Officer Defendants actually believed that use of VIOXX caused serious adverse CV events, and the totality of the facts on which their belief was based, including, *inter alia*, the information referenced in ¶ 219. As a result, investors remained unaware of Merck's and the Officer Defendants' actual beliefs concerning VIOXX's prothrombotic effects, and were materially misled as to the enormous risk that VIOXX's true safety profile would jeopardize (or at least significantly limit) VIOXX's commercial viability and ability to generate substantial revenue for the Company.

F. Materially False and Misleading Statements Made During the Second Half of 2001

226. On July 20, 2001, Merck issued a press release announcing the Company's results for the second quarter 2001 (the period ending June 30, 2001). The July 20, 2001 press release stated:

> Since its 1999 launch, Vioxx has become the world's fastest growing branded prescription arthritis medicine, and it is already Merck's second largest medicine. In 2001, Vioxx achieved new-prescription leadership within the coxib market in the United States, ***demonstrating that physicians continue to recognize the medicine's benefits to the patients***.

> ***New scientific data supporting the efficacy and overall safety profile of VIOXX were presented at medical meetings during the quarter. These data included the results of the ADVANTAGE trial, presented at the Digestive Diseases Week conference in May***.

227. The above-referenced statements from the July 20, 2001 Merck press release concerning VIOXX were materially false and misleading because they failed to disclose that Merck and the Officer Defendants actually believed that use of VIOXX caused serious adverse CV events, and the totality of the facts on which their belief was based, including, *inter alia*, the information referenced in ¶ 219. As a result, investors remained unaware of Merck and the Officer Defendants' actual beliefs concerning VIOXX's prothrombotic effects, and were materially misled as to the enormous risk that VIOXX's true safety profile would jeopardize (or at least significantly limit) VIOXX's commercial viability and ability to generate substantial revenue for the Company.

228. On August 22, 2001, *JAMA* published the findings of the Cleveland Clinic Study, which concluded that VIGOR's CV results could be explained by either a prothrombotic effect of VIOXX or an antithrombotic effect of naproxen, but which stated no conclusion as to which theory was most likely. *See also* ¶ 131 above.

229. On August 21, 2001, *Bloomberg News* quoted Merck's Senior Director of Cardiovascular Clinical Research, Laura Demopoulos, as stating, in anticipation of the publication of the *JAMA* article, that: ***"We [Merck] already have additional data beyond what they cite, and the findings are very, very reassuring. VIOXX does not result in any increase in cardiovascular events compared to placebo."***

230. Similarly, on August 23, 2001, the day after the release of the *JAMA* article, the Merck issued a press release reaffirming that ***"the Company stands behind the overall and cardiovascular safety profile . . . of VIOXX."*** Immediately after the publication of the *JAMA*

article, Merck also sent, by Federal Express, "Dear Doctor" letters to physicians throughout the country that disparaged the *JAMA* article as "not based on any new clinical study," and that assured the physicians that Merck ***"stands behind the overall and cardiovascular safety profile"*** of VIOXX.

231. However, the reassuring statements by Merck concerning VIOXX's cardiovascular safety contained in the August 21, 2001 *Bloomberg News* article and its August 23, 2001 press release were materially false and misleading because (a) they constituted an affirmatively false representation that Merck and the Officer Defendants believed in good faith that it was the naproxen hypothesis (as opposed to VIOXX's prothrombotic effects) that was the most likely explanation of VIGOR's adverse CV results; and (b) failed to disclose that Merck and the Officer Defendants actually believed that use of VIOXX caused serious adverse CV events, and the totality of the facts on which their belief was based, including, *inter alia*, the information referenced in ¶ 219. As a result, investors remained unaware of Merck's and the Officer Defendants' actual beliefs concerning VIOXX's prothrombotic effects, and were materially misled as to the enormous risk that VIOXX's true safety profile would jeopardize (or at least significantly limit) VIOXX's commercial viability and ability to generate substantial revenue for the Company.

232. Subsequent news and analyst reports following the release of the *JAMA* article reflected Merck's efforts to downplay and disparage the *JAMA* article and to reinforce the "naproxen hypothesis" as the correct interpretation of the VIGOR data. For example, on August 22, 2001, Credit Suisse First Boston reported that:

> ***The JAMA researchers themselves point out several significant limitations in their study . . . .We note that the VIGOR trial did not include low-dose aspirin, and that the control drug (naproxen) is known to possess a cardio-protective, anti-platelet***

> ***effect***. This makes it extremely difficult to determine whether the difference in cardiac events seen in VIGOR results from a naproxen 'benefit' or a Vioxx 'liability.'"

233. On September 24, 2001, a *Bloomberg News* report about the September 17, 2001 letter from the FDA's Division of Drug Marketing, Advertising and Communications (the "DDMAC Letter") (*see* ¶¶ 135-136) quoted Merck's spokeswoman Christine Fanelle as stating: "***We continue to stand behind the overall safety and the cardiovascular safety of the product***, but our immediate priority is to discuss our response'' with the FDA.

234. However, the statement set forth above in the September 24, 2001 *Bloomberg News* article, which was intended to, and did, reassure the market concerning VIOXX's cardiovascular safety, was materially false and misleading because (a) it constituted an affirmatively false representation that Merck and the Officer Defendants believed in good faith that it was the naproxen hypothesis (as opposed to VIOXX's prothrombotic effects) that was the most likely explanation of VIGOR's adverse CV results and/or failed to correct a prior false representation; and (b) failed to disclose that Merck and the Officer Defendants actually believed that use of VIOXX caused serious adverse CV events, and the totality of the facts on which their belief was based, including, *inter alia*, the information referenced in ¶ 219. As a result, investors remained unaware of Merck's and the Officer Defendants' actual beliefs concerning VIOXX's prothrombotic effects, and were materially misled as to the enormous risk that VIOXX's true safety profile would jeopardize (or at least significantly limit) VIOXX's commercial viability and ability to generate substantial revenue for the Company.

235. On October 9, 2001, *The New York Times* published an article about COX-2 inhibitors, entitled "The Doctor's World, For Pain Reliever, Questions of Risk Remain Unresolved." The article reported on the continued popularity of VIOXX and Celebrex, but also

noted that questions had been raised as to whether "VIOXX may have an unexpected side effect -- a very slight increase in the risk of heart attack. The risk is hypothesized, not proved." The article, among other things, also quoted defendant Scolnick as stating: "[T]here are two possible interpretations [for the CV results from VIGOR]. . . [n]aproxen lowers heart attack rate, or VIOXX raises it. . . Either COX-2 inhibitors shift the clotting balance, or naproxen, which can impede blood clotting has a positive effect. According to the article, defendant Scolnick added that: "while the Company announced the heart attack findings to doctors and the public, it looked back at its data from studies using different drugs or dummy pills [placebos] in comparison to VIOXX. It found no evidence that VIOXX increased the risk of heart attacks." In addition, the article quoted defendant Scolnick as stating that, ***the company decided that "the likeliest interpretation of that data is that naproxen lowered the thrombotic event rate,***" and that without the theoretical question raised by Dr. FitzGerald, "no one would have a question remaining in their mind that there might be an additional interpretation."

236. However, defendant Scolnick's statement to *The New York Times*, which sought to attribute the difference in thromboembolic events in VIGOR to naproxen's purported cardioprotective characteristics (*e.g.*, "the likeliest interpretation of that [VIGOR] data is that naproxen lowered. . . the thrombotic event rate") were materially false and misleading because (a) it constituted an affirmatively false representation that defendant Scolnick believed in good faith that it was the naproxen hypothesis (as opposed to VIOXX's prothrombotic effects) that was the most likely explanation of VIGOR's adverse CV results; and (b) it failed to disclose that Merck and the Officer Defendants actually believed that use of VIOXX caused serious adverse CV events, and the totality of the facts on which their belief was based, including, *inter alia*, the information referenced in ¶ 219. As a result, investors remained unaware of Merck and the

Officer Defendants' actual beliefs concerning VIOXX's prothrombotic effects, and were materially misled as to the enormous risk that VIOXX's true safety profile would jeopardize (or at least significantly limit) VIOXX's commercial viability and ability to generate substantial revenue for the Company.

237. In addition, defendant Scolnick's statement in the October 9 *New York Times* article to the effect that Merck had "found no evidence that Vioxx increased the risk of heart attacks" was also materially false and misleading because, at the time the statement was made, Merck and the Officer Defendants were in possession of the results of (a) Merck's non-public internal February 1998 analysis, which showed, *inter alia*, that women taking VIOXX had *at least* a 216% (statistically significant) greater risk of experiencing serious adverse cardiovascular events compared to women not taking any drug in other Merck studies; (b) the non-public final results from Merck's Alzheimer's Treatment Trial (Protocol 091), which showed that VIOXX patients had a statistically significant higher rate of deaths than patients treated by placebo on an intention-to-treat basis, on treatment basis, and combined intention-to-treat/on treatment basis; (c) the non-public interim results of Merck's Alzheimer's Prevention Trial (Protocol 078), which showed that VIOXX patients had a statistically significant higher rate of deaths than patients being treated by placebo on an "intention to treat" basis and combined intention-to-treat/on treatment basis; and (d) the non-public aggregated results of Merck's Alzheimer's trials, which showed that patients taking VIOXX had a statistically significant higher rate of heart disease death. As a result, investors were further materially misled as to the enormous risk that VIOXX's true safety profile would jeopardize (or at least significantly limit) VIOXX's commercial viability and ability to generate substantial revenue for the Company.

238. On December 11, 2001, Merck issued a news release reporting that, during its Annual Business Briefing to update approximately 300 securities analysts on the status of the Company, Merck "announced plans to conduct a large cardiovascular clinical outcomes study with Vioxx." According to a *Bloomberg News* article of that day, at the Annual Business Briefing defendant Scolnick explained that Merck will conduct such research on VIOXX so it can be "100 percent sure" of VIOXX's safety. Defendant Scolnick additionally falsely reassured the market: "Whatever the answer is in these studies, we will report it to the world."

239. By having chosen to speak about VIOXX's cardiovascular safety, Merck and the Officer Defendants had a duty to speak fully and truthfully on that subject. However, in violation of that duty, the above-referenced statements from December 11, 2001 were materially misleading because (a) they failed to disclose that Merck and the Officer Defendants actually believed that use of VIOXX caused serious adverse CV events, and the totality of the facts on which their belief was based, including, *inter alia*, the information referenced in ¶ 219; and (b) as discussed further below, at ¶¶ 241-243, in mid-March 2002, Merck decided to cancel its large-scale VIOXX clinical outcomes study due to VIOXX's prothrombotic effects, but Merck did not update or correct its December 11, 2001 statements (or any future statements Merck made about VIOXX) in order to inform the market of the cancellation of the large-scale VIOXX cardiovascular outcomes study. As a result, investors remained unaware of Merck and the Officer Defendants' actual beliefs concerning VIOXX's prothrombotic effects and the true status of the large-scale VIOXX clinical outcomes trial, and were materially misled as to the enormous risk that VIOXX's true safety profile would jeopardize (or at least significantly limit) VIOXX's commercial viability and ability to generate substantial revenue for the Company.

H. Materially False and Misleading Statements Made During the First Half of 2002

240. On March 15, 2002, Merck and the Officer Defendants were forced to withdraw the original NDA for ARCOXIA, thereby putting further pressure on Defendants to conceal their beliefs about the adverse cardiovascular profile of its blockbuster drug VIOXX. As a result, Merck's dependence on VIOXX for its future revenues significantly increased.

241. In March 2002, Merck and the Officer Defendants secretly halted the cardiovascular clinical study it previously announced to blunt criticism of VIOXX's health risks, which defendant Scolnick stated would have provided "100 percent" assurance of VIOXX's safety. *The New York Times,* in an article entitled "Merck Canceled an Early Study of VIOXX," which was published after the Class Period (on February 8, 2005), reported that "previously undisclosed company documents show that the drug maker was poised to begin a major cardiovascular study of [VIOXX] in 2002, and abruptly dropped the project before it was set to start."

242. The *New York Times* reported:

> [M]erck has never disclosed how extensively it planned that study, which was known inside the company as the Valor trial, or how close it came to starting it. ***By early 2002, the drug maker had already contacted outside researchers to oversee the test, had approached a competing drug maker to obtain anti-ulcer drugs to ease the possibility of side effects, and had prepared a 70-page protocol that spelled out how the test was to be conducted, according to documents reviewed by The New York Times***.
>
> One planning document, for example, shows that the first patients were supposed to enter the study in June 2002 and the last patient was to leave it in January 2004. But in mid-March 2002, just days before company researchers had planned to submit the study's protocol to the F.D.A., top executives of the drug maker ordered work on the project halted. It was never revived.
>
> "I have the unpleasant task of having to inform you that the VIOXX CV Outcomes Study has been placed on hold," a memo

> dated March 13, 2002, and sent to dozens of Merck employees worldwide, stated. "***At this time we do not have any of the details that led to this decision, however, we have been informed that upper management is in the process of reviewing the various study options***."
>
> * * *
>
> Asked to provide a copy of a document from March 2002 which summarized the decisions given at the time for not going forward with the study, [a Merck spokeswoman] said that no such document existed.

243. The timing of Merck and the Officer Defendants' decision to call off the Valor Study is also significant. *The New York Times* reported:

> Work on the Valor trial was halted at the same time that officials from Merck and the F.D.A. were concluding lengthy and heated negotiations over how Vioxx's label would reflect data from an earlier trial, known as the Vigor study, which indicated that the widely used painkiller posed potential cardiovascular risks.

244. On April 11, 2002, Merck issued a press release announcing that the FDA had "approved changes to the prescribing information [*i.e.*, the label leaflet] for VIOXX . . . to include results from the landmark 8,000 patient [VIGOR] Study." Merck also stated that "[t]he prescribing information also has been revised to include cardiovascular data from VIGOR." The press release, however, also went on to falsely assure investors once again that VIOXX was safe, quoting defendant Scolnick as stating that: "***Merck is confident in the . . . safety profile of VIOXX.***"

245. However, the statement in the April 11, 2002 Merck press release, which reassured investors concerning VIOXX's purported lack of cardiovascular risks, was materially false and misleading because (a) it constituted an affirmatively false representation that Merck and the Officer Defendants believed in good faith that it was the naproxen hypothesis (as opposed to VIOXX's prothrombotic effects) that was the most likely explanation of VIGOR's

adverse CV results and/or failed to correct a prior false representation; and (b) failed to disclose that Merck and the Officer Defendants actually believed that use of VIOXX caused serious adverse CV events, and the totality of the facts on which their belief was based, including, *inter alia*, the information referenced in ¶ 219. As a result, investors remained unaware of Merck's and the Officer Defendants' actual beliefs concerning VIOXX's prothrombotic effects, and were materially misled as to the enormous risk that VIOXX's true safety profile would jeopardize (or at least significantly limit) VIOXX's commercial viability and ability to generate substantial revenue for the Company.

246. Merck's numerous materially false and misleading statements of opinion or belief concerning VIOXX's adverse safety profile, which jeopardized the commercial viability of the drug and put the franchise at risk, were not limited to the SEC filings, press releases, and conference calls with securities analysts detailed herein. Instead, Merck also included materially false or misleading statements in VIOXX's labeling leaflet (which is the multi-page, small print pamphlet inserted in the box in which a pharmaceutical product is sold, as opposed to the "sticker" that is attached to the container of the product itself).

247. Labeling leaflet information with respect to a major product is regularly considered by analysts and other financial market participants in assessing a company's business, products, and prospects. Securities analysts who specialize in pharmaceutical companies study product label leaflets as part of their analysis of a drug's commercial viability, long-term growth and revenue prospects, and potential for product liability exposure. Thus, truthful labeling is an essential component of the market's valuation of the performance and prospects of a pharmaceutical company, including but not limited to discounted cash flow, as well as the company's securities.

248. The label leaflets for VIOXX did not include any reference whatsoever to any possible cardiovascular side effects attributable to VIOXX in the "Precautions" section (let alone in the more serious "Contraindications" or "Warnings" sections) prior to the release of a new label on or about April 12, 2002. Those pre-April 2002 label leaflets were materially false and misleading because they failed to disclose that Merck's senior scientists actually believed that use of VIOXX caused serious adverse CV events, and the totality of the facts on which that belief was based.

249. Moreover, even after the VIOXX label was changed on April 12, 2002 "to include cardiovascular data from VIGOR" (as well as VIGOR's purported beneficial GI findings), that label (the "April 12, 2002 Label") contained materially false and misleading statements concerning VIOXX's safety profile. Among other things, the April 12, 2002 Label stated the following:

> The information below should be taken into consideration and caution should be exercised when VIOXX is used in patients with a medical history of ischemic heart disease:
>
> In VIGOR, a study in 8076 patients (mean age 58; VIOXX n=4047, naproxen n=4029) with a median duration of exposure of 9 months, the risk of developing a serious cardiovascular thrombotic event was significantly higher in patients treated with VIOXX 50 mg once daily (n=45) as compared to patients treated with naproxen 500 mg twice daily (n=19). In VIGOR, mortality due to cardiovascular thrombotic events (7 vs 6, VIOXX vs naproxen, respectively) was similar between the treatment groups. (See CLINICAL STUDIES, Special Studies, VIGOR, Other Safety Findings: Cardiovascular Safety.) In a placebo-controlled database derived form 2 studies with a total of 2142 elderly patients (mean age 75; VIOXX n-1067, placebo n=1075) with a median duration of exposure of approximately 14 months, the number of patients with serious cardiovascular thrombotic events was 21 vs 35 for patients treated with VIOXX 25 mg once daily versus placebo, respectively. In these same 2 placebo-controlled studies, mortality due to cardiovascular thrombotic events was 8 vs 3 for VIOXX versus placebo, respectively. The significance of the cardiovascular findings from these 3 studies (VIGOR and 2 placebo-controlled studies) is unknown. Prospective studies specifically designed to compare the incidence of serious CV events in

> patients taking VIOXX versus NSAID comparators or placebo have not been performed (emphasis added).

250. The April 12, 2002 Label was materially false and misleading. Merck's mortality data from "2 placebo-controlled studies" showing 8 events on VIOXX compared to 3 on placebo referenced the mortality rates in Protocols 078 plus 091 using on-drug confirmed cardiovascular deaths as of March 16, 2001, the cutoff date for the April 12, 2002 labeling approval. However, as of March 16, 2001, confirmed cardiovascular deaths using ITT were 10 vs. 3 for VIOXX vs. placebo, and as of the actual date of the labeling approval, confirmed cardiovascular deaths using ITT were 17 vs. 5 for VIOXX versus placebo. Both results were statistically significant. The label failed to disclose that Merck and the Officer Defendants had in their possession as of the labeling approval cutoff date data that showed that use of VIOXX caused a statistically significant increase in cardiovascular deaths. The April 12, 2002 Label was also materially false and misleading because it failed to disclose that Merck actually believed that use of VIOXX caused serious CV events, and the totality of facts on which its belief was based, including, inter alia, the information referenced in ¶ 225. As a result, investors remained unaware of Merck's and the Officer Defendants' actual beliefs concerning VIOXX's prothrombotic effects, and were materially misled as to the enormous risk that VIOXX's true safety profile would jeopardize (or at least significantly limit) VIOXX's commercial viability and ability to generate substantial revenue for the Company.

251. On April 18, 2002, subsequent to the release of the results for the first quarter of 2002, Merck held a conference call for analysts, money and portfolio managers, institutional investors, and large Merck shareholders. During the call, Merck spokesman Mark Stejbach commented on the "new labeling changes" to VIOXX, which purportedly included the results from VIGOR:

> ***[I]mportantly there was a change to the precautions, again not the warnings, but the precautions regarding cardiovascular language and two effects there, there were the results of the VIGOR study that had been disclosed for some time that you all know about.*** And that showed a lower cardiovascular event rate for naproxen vs. VIOXX in the VIGOR Study. And importantly, also in the label now are the results of the safety results of two large placebo control studies in a large elderly population. And in that study we saw essentially no difference between VIOXX and placebo on the rate of cardiovascular. ***In fact, numerically VIOXX is even a little lower. But this is very reassuring and we think its part of the body of evidence that supports our belief that the effect seen in VIGOR were the results of the anti-platelet effect of naproxen***. Of course, VIOXX does not have an effect on platelets consistent with its selective inhibition and that's reflected in the label. And so appropriate patients should be given anti-platelet therapy. ***So, I think that's a position Merck has always had and now its quite clearly laid out in the labeling***.

252. However, the statements made during Merck's April 18, 2002 conference call, which sought to attribute the difference in thromboembolic events in VIGOR to naproxen's purported cardioprotective characteristics (the "naproxen hypothesis"), were materially false and misleading because (a) it constituted an affirmatively false representation that Merck and the Officer Defendants believed in good faith that it was the naproxen hypothesis (as opposed to VIOXX's prothrombotic effects) that was the most likely explanation of VIGOR's adverse CV results and/or failed to correct a prior false representation; and (b) failed to disclose that Merck and the Officer Defendants actually believed that use of VIOXX caused serious adverse CV events, and the totality of the facts on which their belief was based, including, *inter alia*, the information referenced in ¶ 219. As a result, investors remained unaware of Merck's and the Officer Defendants' actual beliefs concerning VIOXX's prothrombotic effects, and were materially misled as to the enormous risk that VIOXX's true safety profile would jeopardize (or at least significantly limit) VIOXX's commercial viability and ability to generate substantial revenue for the Company.

253. On or about May 13, 2002, Merck filed with the SEC Merck's Form 10-Q for the first quarter 2002, which was signed by defendants Frazier and Henriques. The Form 10-Q contained substantially the same materially false and misleading statements concerning the purported success and safety of VIOXX that were made in the Company's April 18, 2002 press release referred to above.

I. Materially False and Misleading Statements Made During the Second Half of 2002

254. On October 18, 2002, subsequent to the release of its results for the third quarter of 2002, Merck held a conference call for analysts, money and portfolio managers, institutional investors, and large Merck shareholders. During the call, a participant asked the Merck spokesperson the following question: "Ed Scolnick last December had basically told us there would be a VIOXX cardiovascular safety study performed, what's the status of beginning that trial or have those plans been abandoned?" In response, the Merck spokesperson stated:

> In terms of the cardiovascular outcome studies, you're right that we discussed doing those studies and ***we have not abandoned them***, in fact, we're continuing to make progress on those, it's a very complex area as you all know and we're researching this area . . . . [S]o we'll continue with some of these ongoing things, continue to update the scientific community, but I know… we are still planning cardiovascular outcome studies for Vioxx and look forward to, hopefully soon, be able to discuss that in more detail and in a comprehensive manner across the products. Okay, so with that I apologize, we've run over. . . .

255. Merck and the Officer Defendants' statements during the third quarter 2002 conference call that Merck was "continuing to make progress" on the cardiovascular outcome studies was materially false and misleading because, unbeknownst to investors, Merck had already cancelled its cardiovascular outcomes study, as set forth in ¶¶ 241-243 above.

J. Materially False and Misleading Statements Made During the Second Half of 2003

256. On or about August 15, 2003, Merck issued a new VIOXX label that included a brief description of an aspirin endoscopy study. The new label, however, was otherwise substantively unchanged, and was therefore materially false and misleading for the same reasons as set forth above in ¶ 250 above.

257. As previously discussed in ¶¶ 172-174 above, during the fall of 2003 there were published reports of new data suggesting that VIOXX "might slightly raise the risk of heart attacks" and might "not have any greater efficacy than traditional NSAIDS," followed by an October 30, 2003 *Wall Street Journal* article which reported that the Brigham Study had found an increased risk of heart attack in patients taking VIOXX compared to patients taking Celebrex or placebo.

258. On November 2, 2003, in response to the October 30, 2003 *Wall Street Journal* article, defendant Reicin publicly stated that "In [Merck's] placebo-controlled randomized trials, we have found no significant difference between VIOXX and placebo." Defendant Reicin also sought to disparage the Brigham Study results by stating: "Randomized clinical trials are the 'gold standard,' and this isn't such a trial."

259. Similarly, in a letter to the editor of *The Wall Street Journal* entitled "Merck Stands Behind The Safety of VIOXX" which was published on November 5, 2003, Peter Kim, then-President of Merck Research Laboratories, also sought to disparage the Brigham Study results while reaffirming Merck's purported belief that VIOXX was safe and was not prothrombotic. As Kim stated in his letter to the editor:

> ***Nothing is more important to Merck than the safety of its medicines. Your Oct. 30 story about an observational analysis of Vioxx was incomplete***. The article discussed only the findings from this analysis where Vioxx appeared to have an unfavorable

> risk profile, but failed to report other findings from the same analysis that showed no statistically significant difference in the risk of heart attack for Vioxx compared with other commonly used anti-inflammatory drugs.
>
> The story also failed to report that another observational analysis presented at the same scientific meeting also showed no statistically significant difference in heart attacks between Vioxx and two widely used anti-inflammatory drugs, ibuprofen and diclofenac. ***A complete reporting of the data presented might have remedied the mistaken impression left by the story.***
>
> Observational methods lack the rigor of randomized, controlled clinical trials, and have led the scientific community astray before. For example, decades of observational analyses suggested that hormone replacement therapy reduced heart disease risk in post-menopausal women, but the landmark Women's Health Initiative, a randomized, controlled trial, found the opposite with an estrogen progestin combination. That is why observational studies must be interpreted with caution. ***Merck stands behind the safety of Vioxx based on the results of numerous randomized, controlled clinical trials.***
>
> Finally, it should be noted that Merck has previously announced it is conducting large prospective, randomized placebo-controlled clinical trials that, when added to the extensive data from clinical trials already available, will provide an even more comprehensive picture of the cardiovascular safety profile of Vioxx.

260. However, defendant Reicin's November 2, 2003 statements and Merck's November 5, 2003 statements were materially false and misleading because (a) they constituted affirmatively false representations that Merck and Reicin believed in good faith that it was the naproxen hypothesis (as opposed to VIOXX's prothrombotic effects) that was the most likely explanation of VIGOR's adverse CV results and/or failed to correct a prior false representation; and (b) failed to disclose that Merck and Reicin actually believed that use of VIOXX caused serious adverse CV events, and the totality of the facts on which their belief was based, including, *inter alia*, the information referenced in ¶ 219. As a result, investors remained unaware of Merck's and Reicin's actual beliefs concerning VIOXX's prothrombotic effects, and

were materially misled as to the enormous risk that VIOXX's true safety profile would jeopardize (or at least significantly limit) VIOXX's commercial viability and ability to generate substantial revenue for the Company.

K. Materially False and Misleading Statements Made During the First Half of 2004

261. On March 10, 2004, *Bloomberg News* reported that a study funded by Pfizer, which examined possible risks posed by various painkillers, found that VIOXX was linked to a higher risk of heart attack for patients with high blood pressure. Continuing Merck's effort to negate, minimize, and discredit any link between VIOXX and increased cardiovascular risk, according to the *Bloomberg News* report, Merck spokeswoman Mary-Elizabeth Blake stated that "***the company disagrees with the findings***" and that "the study wasn't designed well."

262. However, the statements in Merck's March 10, 2004 press release, which reassured the market concerning VIOXX's purported lack of cardiovascular risks, were materially false and misleading because (a) they constituted an affirmatively false representation that Merck believed in good faith that it was the naproxen hypothesis (as opposed to VIOXX's prothrombotic effects) that was the most likely explanation of VIGOR's adverse CV results and/or failed to correct a prior false representation; and (b) failed to disclose that Merck actually believed that use of VIOXX caused serious adverse CV events, and the totality of the facts on which their belief was based, including, *inter alia*, the information referenced in ¶ 219 above. As a result, investors remained unaware of Merck's actual beliefs concerning VIOXX's prothrombotic effects, and were materially misled as to the enormous risk that VIOXX's true safety profile would jeopardize (or at least significantly limit) VIOXX's commercial viability and ability to generate substantial revenue for the Company.

263. On or about April 6, 2004, Merck issued a new VIOXX label that stated VIOXX had been approved for the acute treatment of migraines for adults. The new label, however, was otherwise substantively unchanged, and was therefore materially false and misleading for the same reasons as set forth above in ¶ 250 above.

L. Materially False and Misleading Statements Made During the Second Half of 2004

264. On August 26, 2004, Merck moved immediately to refute and discredit the Kaiser Study and to reassure investors as to VIOXX's safety by issuing a statement on the *Business Wire*. The August 26 statement averred as follows:

> ***Merck strongly disagrees with the conclusions of an observational analysis by Graham et al, presented at an international medical meeting this week, which evaluated the rate of cardiovascular events in patients taking COX-2 specific inhibitors VIOXX (rofecoxib) and Celebrex (celecoxib) and in patients taking non-selective NSAIDs.*** This analysis is a retrospective database analysis -- not a clinical trial. Observational analyses have limitations, often conflict with each other, and must be interpreted within the context of data from large, randomized, controlled clinical trials.

The August 26, 2004 statement also quoted Merck's Peter Kim as stating:

> This retrospective analysis is based only on a database review. Observational analyses do not have the rigor of randomized, controlled clinical trials. The robust clinical trial data available support the safety of VIOXX. ***Based on all of the data that are available from our clinical trials, Merck stands behind the efficacy and safety, including cardiovascular safety, of VIOXX . . . . Nothing is more important to Merck than the safety of our medicines***.

265. The August 26, 2004 statements reported by *Business Wire*, including Merck's statement that "Merck stands behind the efficacy and safety, including cardiovascular safety, of VIOXX," were materially false and misleading because they (a) constituted an affirmatively false representation that Merck believed in good faith that it was the naproxen hypothesis (as

opposed to VIOXX's prothrombotic effects) that was the most likely explanation of VIGOR's adverse CV results and/or failed to correct a prior false representation; and (b) failed to disclose that Merck actually believed that use of VIOXX caused serious adverse CV events, and the totality of the facts on which its belief was based, including, *inter alia*, the information referenced in ¶ 219 above. As a result, investors remained unaware of Merck's actual beliefs concerning VIOXX's prothrombotic effects, and were materially misled as to the enormous risk that VIOXX's true safety profile would jeopardize (or at least significantly limit) VIOXX's commercial viability and ability to generate substantial revenue for the Company.

266. On August 27, 2004, the *San Jose Mercury News* quoted Merck spokesperson Mary Elizabeth Blake responding to the Kaiser Permanente study by stating: "***We are certainly confident in the efficacy and safety of VIOXX.***" This statement was also materially false and misleading for the same reasons as stated in the immediately preceding paragraph.

267. On September 30, 2004, Merck issued a press release announcing that, "effective immediately," the Company was withdrawing VIOXX worldwide in light of the recommendation of the External Safety Monitoring Board for the APPROVe study that the study be stopped based on the increased risk of confirmed cardiovascular events they found in patients taking VIOXX.

268. That same day, Merck also held a conference call for analysts to further discuss the withdrawal. During the call, then-CEO Gilmartin stated:

> We are taking this action because we believe it serves the interests of patients . . . We believe it would have been possible to continue to market VIOXX with labeling that would incorporate these new data. However, given the availability of alternative therapies and the questions raised by the data, ***we concluded that a voluntary withdrawal is the responsible course to take***.

X. ADDITIONAL SCIENTER ALLEGATIONS

269. As alleged herein, Merck and the Officer Defendants acted with scienter in that they knew, or recklessly disregarded with deliberate recklessness, that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew or recklessly disregarded that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violators of the federal securities laws.

270. For example, the following allegations strongly support a finding that Merck and the Officer Defendants acted with scienter:

(A) Merck and the Officer Defendants reviewed and/or had access to the unpublished original version of Drs. Garrett FitzGerald and Francesca Catella-Lawson's article reporting on the results of Protocol 023, and thereafter pressured Drs. FitzGerald and Catella-Lawson to "tone down" their conclusions in the published 023 version. *See* ¶¶ 73-75.

(B) In a February 1997 email, Merck scientist Dr. Briggs Morrison, an author of the article reporting the results of Protocol 023 and one of the Merck scientists who pressured Drs. FitzGerald and Catella-Lawson to "tone down" their conclusions, wrote defendant Reicin and other senior Merck scientists warning them that their proposed design for the planned GI outcomes trial was faulty because "without COX-1 inhibition, you will get more thrombotic events and kill [the] drug." *See* ¶ 77.

(C) Defendant Reicin, in a February 1997 email, admitted that "the possibility of increased CV events is of great concern" and remarked on her reluctance to "be the one to present those results to senior management." *See* ¶ 79.

(D) Defendant Reicin, in the same February 1997 email, proposed that Merck design the GI trial to "exclude[e] high risk CV patients" in the hopes of "decreas[ing] the CV event rate so that a difference between the two groups would not be evident." *See* ¶ 80.

(E) The Officer Defendants were senior officers of Merck and, as evidenced by defendant Reicin's February 1997 email that she couldn't "wait to be the one to tell management" about the serious concerns of those in Merck Research Laboratories about VIOXX's prothrombotic characteristics (which would "kill the drug"), Merck's senior management was closely involved in the production and development of the Company's blockbuster drug. *See* ¶ 79.

(F) Merck and the Officer Defendants cancelled two GI outcome studies for fear that they would show VIOXX to be prothrombotic and "kill the drug." *See* ¶ 82.

(G) The Officer Defendants reviewed and/or had access to the Company's internal February 1998 analysis showing that women in the VIOXX osteoarthritis trials had a statistically significant 216% increase in serious adverse cardiovascular events. *See* ¶¶ 87-90.

(H) The Officer Defendants chose not to share the Company's internal February 1998 analysis with either Merck's Board of Scientific Advisors or the public. *See* ¶¶ 91-92.

(I) The Officer Defendants intentionally designed the VIGOR trial to exclude patients at high risk of a heart attack in order to minimize the risk that the results would show that VIOXX was prothrombotic. *See* ¶ 99.

(J) The Officer Defendants ordered that Merck scientists stop working on creating a data analysis plan for cardiovascular events in VIGOR, and not make comparisons between VIOXX and other comparator drugs, despite the fact that Merck's Board of Scientific Advisors had recommended that this be done for all VIOXX trials and that the protocol for VIGOR called for such a data analysis plan. *See* ¶ 106.

(K) The Officer Defendants deliberately staffed at least half of the VIGOR DSMB with a combination of physicians who had financial conflicts of interest with Merck and a full-time Company employee who reported to defendant Scolnick. *See* ¶ 101.

(L) The Officer Defendants deliberately chose not to assign a cardiologist to VIGOR's DSMB. *See* ¶ 99.

(M) The Officer Defendants took efforts to avoid complying with the DSMB's request that Merck analyze the cardiovascular events in VIGOR as provided for in the trial protocol. *See* ¶ 107.

(N) Defendant Scolnick, Merck's then-President of Merck Research Laboratories, requested a confidential meeting with the purportedly "blinded" statistician for VIGOR (Merck Scientist Deborah Shapiro) *the day after* the premature cardiovascular (as opposed to GI) cut-off for VIGOR because, as he emphasized

in his March 2001 email to her that attached a securities analyst report, "this situation cannot simply follow the 'book' ways of my knowing." *See* ¶ 109.

(O) Defendant Scolnick acknowledged, *albeit* solely within the confines of the Company's walls, that VIOXX was the cause of the increased rate of adverse cardiovascular events in VIGOR -- *i.e.*, that it was "mechanism-based as we worried it was." *See* ¶ 110.

(P) Defendants Scolnick and Reicin, and other senior Merck scientists, conceded to one another that their frantic efforts to find support for the naproxen hypothesis following their receipt of the VIGOR cardiovascular results were unsuccessful. *See* ¶ 113.

(Q) The Officer Defendants, unlike the market, were in possession of and had access to "the best comparative clin[ical] data on MI [heart attack] and NSAIDs," which confirmed that aspirin significantly reduced the risk that patients might suffer a first, nonfatal heart attack, but that naproxen, ibuprofen, and diclofenac (*i.e.*, other traditional NSAIDs) "had no significant effect," either individually or combined, on the risk of suffering a heart attack. *See* ¶¶ 115-117.

(R) Defendant Reicin pressured Merck scientists to reclassify the "cause of death" for at least one patient in the ADVANTAGE study so it would not "raise concerns." *See* ¶ 145.

(S) Merck changed the pre-announced (and customary) "intention-to-treat" and "on treatment" methodologies for analyzing data from the Alzheimer's trials after they determined that the (non-public) statistically significant results highlighted the fact that VIOXX was unsafe. *See* ¶¶ 148-166.

(T) Merck and the Officer Defendants failed to disclose the statistically significant mortality data from Merck's Alzheimer's trials to investors. *See* ¶¶ 148-166.

(U) Merck and the Officer Defendants attempted to have the name of a Merck scientist secretly removed from the publication of the Brigham Study, in order to try to distance Merck from the study's adverse cardiovascular finding. *See* ¶¶ 177-178.

(V) The Officer Defendants framed Merck's public statements regarding the safety of VIOXX to falsely promote the naproxen hypothesis and otherwise mislead investors as to the true facts about VIOXX.

271. In addition, the fact that Merck and the Officer Defendants pressured and/or attempted to intimidate academics and others who were critical of VIOXX (as first made public by the media in November 2004) further supports a strong inference of scienter. From the outset of the Class Period, Merck sought to either co-opt (through offers of research grants, paid memberships on advisory boards, etc.) or silence critics of VIOXX. For example, an internal Merck email dated April 29, 1999 from Merck marketing manager Susan Baumgartner to colleagues in Merck's marketing department, which was not disclosed to the public until after the Class Period, provides a "list of 'problem' physicians that we must, at a minimum, neutralize."

272. Similarly, a July 23, 1999 internal Merck email from Ms. Baumgartner to Merck's Regional Managing Directors references Merck's efforts to sway the "most challenging (and also some of the most vocal and influential) national and regional physicians for VIOXX." As the email notes, these physicians "have [been] identified as being 1) Important from a business perspective in terms of influence and/or prescribing, and 2) Not as supportive of Merck

and/or VIOXX as we would like." Baumgartner proceeded to note that "some of these physicians have already been 'neutralized.'" While Baumgartner's email focused on ways to co-opt physicians who were "not as supportive of Merck and/or VIOXX as [Merck] would like," through means such as giving them grants, employing them to do research, and other funding mechanisms, Merck also engaged in far more nefarious tactics with academics and physicians for whom Merck's efforts were unsuccessful. As first revealed in the November 1, 2004 *Wall Street Journal* article, Merck repeatedly attempted to intimidate, pressure and/or outright threaten academic researchers who began to question VIOXX's safety.

273. In addition, as revealed in an April 16, 2008 *JAMA* article entitled "Guest Authorship and Ghostwriting in Publications Related to Rofecoxib," Merck routinely and repeatedly authored drafts of manuscripts of scientific articles or contracted with vendors to draft review articles, and then sought out external academics (*i.e.,* ghost writers) who were willing to be identified as lead authors for these articles, for the purpose of misleading the medical community and investors into believing that these external academics had done research that supported Merck's "naproxen hypothesis." For example, the April 2008 *JAMA* article noted that the article presenting the results of the Prevention Trial (in Alzheimer's patients) -- which had been designed and conducted principally by Merck scientists -- was largely written by Merck scientists and not the attributed first author. Indeed, in an internal Merck email dated January 27, 2004, Merck scientist Eric Yuen told fellow Merck scientist Christopher Lines that "I think you should be the first author since you have done virtually all of the writing." In response, Lines stated "I'm just wondering whether, given the nature of the results and target journal, it's more appropriate to have someone who's a neurologist as first author?" The authors of the April 2008 *JAMA* article noted that a neurologist from the University of California San Diego was recruited

to be the "lead author" of the final article -- and the final article "authored" by this neurologist contained only "minor differences in language and organization between the draft and final versions of the manuscript (particularly in the abstract as opposed to the text)" and that "the trial itself and the analyses were complete before the academically affiliated investigators were involved in the manuscript."

274. As the "lead author" of the October 2003 *Annals* article, which published the results of ADVANTAGE, told *The New York Times* in 2005:

> Merck designed the trial, paid for the trial, ran the trial … Merck came to me after the study was completed and said, 'We want your help to work on the paper.' The initial paper was written at Merck, and then was sent to me for editing.

When this "first author" was later confronted about Merck's improper adjudication of causes of patient deaths in ADVANTAGE, he responded that he was unaware of any such conduct and that "*Basically, I went with the cardiovascular data that was presented to me*."

275. In addition to all of the foregoing, Merck and the Officer Defendants each had powerful motives and the opportunity to perpetrate the fraudulent scheme and course of business described herein. For example:

(A) The central importance of VIOXX to the overall performance and prospects of the Company gave the Officer Defendants a powerful motive to suppress the truth to avoid any adverse impact on VIOXX's commercial viability and prospects.

(B) That the patents on a number of Merck's best selling products were set to expire made the success of VIOXX all the more critical to Merck and the Officer Defendants. Specifically, Merck was set to lose $5 billion in annual revenue as *five* of Merck's best-selling drugs (Vasotec, Pepcid, Mevacor, Prilosec and Prinivil) were all scheduled to lose patent protection between August 2000 and

the end of 2001. Disclosure of adverse facts concerning VIOXX would have further threatened VIOXX's drug pipeline.

(C) VIOXX was Merck's second best selling pharmaceutical product in 2000, 2001, 2002, and 2003, generating billions of dollars in worldwide sales for the Company. Merck described VIOXX as a "driving force" behind the Company's performance. VIOXX accounted for between 10% and 12.5% of Merck's pharmaceutical sales during the Class Period. Accordingly, the Officer Defendants had an obvious motive to delay as long as possible their true beliefs about VIOXX's safety and commercial prospects to avoid jeopardizing its sales, which were so critical to the Company's performance.

(D) The Officer Defendants were also motivated to conceal their true beliefs concerning VIOXX's prothrombotic characteristics from the market because of problems that the Company was experiencing with ARCOXIA, the Company's planned successor to VIOXX. On March 15, 2002, the Officer Defendants were forced to withdraw the NDA for ARCOXIA. Thus, again, Merck and the Officer Defendants had a clear motive to keep the market in the dark for as long as possible with respect to their true beliefs concerning VIOXX's safety profile so that Merck could continue to reap profits from VIOXX.

(E) Because naproxen and other traditional NSAIDs sell for a fraction of the price of VIOXX, and because VIOXX is no more effective than traditional NSAIDs at treating inflammation and pain, the disclosures of the serious safety risks associated with VIOXX would have significantly jeopardized its commercial prospects.

(F) Similarly, any disclosure of the Officer Defendants' true beliefs about VIOXX's safety profile would have put it at a strong disadvantage with respect to Celebrex, which was being actively promoted by Pfizer and Monsanto and had the advantage of being approved by the FDA approximately six months before VIOXX was approved.

(G) As detailed below, defendant Scolnick profited personally from the wrongdoing alleged herein by selling hundreds of thousands of shares of Merck stock at artificially inflated prices, as detailed below, for total proceeds of more than $32.4 million.

(H) The Officer Defendants clearly had the opportunity to commit the fraudulent conduct alleged herein. The Officer Defendants were all members of Merck's senior management who controlled the Company's public statements during the Class Period.

276. As mentioned above, during the Class Period, defendant Scolnick sold substantial amounts of Merck common stock from his personal holdings while in possession of adverse non-public information about VIOXX's safety profile and its commercial prospects. Defendant Scolnick's insider sales often immediately followed the exercise of options to purchase Merck common stock. Stock options provide the grantee with the right to purchase the company's stock at the exercise price and then sell those shares in the open market at the then-prevailing market price. Thus, option holders benefit most from exercising options and selling their shares when they believe the market value of the stock (*i.e.*, the price they will receive when selling the stock in the open market) is at a high point, or when they believe that subsequent events or disclosures will lower the value of their shares. As discussed below, defendant Scolnick's insider sales

occurred at relative high points during the Class Period at prices of $85.00 per share (near the Class Period high closing price of $94.88), which exceeded the closing price of Merck stock on the day the Company disclosed the worldwide withdrawal of VIOXX (*i.e.*, $33.00 on September 30, 2004). Defendant Scolnick's insider sales resulted in instantaneous net profits of ***$24.8 million***.

277. Defendant Scolnick's stock sales were unusual because of the: (i) numbers of shares sold; (ii) dollar amounts of the transactions, and (iii) percentages of his holdings sold, which were very large and far exceeded prior trading patterns. Moreover, defendant Scolnick made ***zero*** open market purchases of Merck stock during the Class Period.[25]

278. Merck's Compensation and Benefits Committee maintained important guidelines regarding the number of Merck shares the Company's Chief Executive Officer and other key executives were expected to hold. Those guidelines significantly narrowed the percentages of stock the executives could sell at any given moment. As the Company's Proxy Statements filed in 1999, 2000 and 2001 all stated, in sum and substance:

> The [Compensation and Benefits] Committee expects the CEO to ***hold 70%*** and the other executive officers named in the Summary Compensation Table to ***hold 60% of the shares which may be purchased from the gain on stock option exercise after deducting option price, taxes and transaction costs***.

In the Company's Proxy Statements filed in 2002 and 2003, the wording was changed to read, in sum and substance:

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[25] Certain Merck executives' holdings in Merck stock options increased during the Class Period through option grants by the Compensation and Benefits Committee of the Merck Board of Directors. These option grants increased such executives' motive to increase Merck's stock price. However, since defendant Scolnick was not a member of Merck's Compensation and Benefits Committee during the Class Period, he did not control the option grants, and any acquisition of options by defendant Scolnick cannot support an inference that Scolnick believed Merck had a positive outlook for the future.

> The [Compensation and Benefits] Committee expects the CEO and other executive officers named in the Summary Compensation Table to ***hold Merck Common Stock in an amount representing a multiple of base salary. For the CEO, the multiple is ten; for the other executive officers, the multiple is five***. The Committee further expects that, until such multiples are reached, the CEO and the other executive officers ***hold a proportion of shares that may be purchased from the net gain on stock option exercise, after deducting exercise price, taxes and transaction costs***. For the CEO, the proportion is ***70%***; for the other executive officers, the proportion is ***60%***.

279. In the Company's Proxy Statement filed in 2004, the wording was further changed to read:

> The [Compensation and Benefits] Committee expects senior management globally (about 200 employees), including the Chief Executive Officer and other executive officers named in the Summary Compensation Table, to ***hold Merck Common Stock in an amount representing a multiple of base salary. For the Chief Executive Officer, the multiple is ten; for the other executive officers, the multiple is five.*** The Committee further expects that, until such multiples are reached, employees covered by the guidelines ***hold a proportion of shares that may be purchased with the net gain from the exercise of stock options, after deducting the exercise price, taxes and transaction costs***. For the Chief Executive Officer, the proportion is ***70 percent***; for the other executive officers, the proportion is ***60 percent***.

280. The Compensation and Benefits Committee, which controlled senior Merck executives' compensation, thus stated publicly to Merck investors that it "expected" the CEO (Gilmartin) and other members of senior management (including defendant Scolnick) to ***hold*** large percentages of their Merck stock. This restricted these individuals' ability to sell large portions of their shares at any given time. This "expectation" essentially prevented these defendants from selling all of their Merck shares at any one time while they served in senior

management positions at the Company, as such a sale would contravene the stated policies of the Committee.[26]

281. While in possession of material adverse non-public information regarding Merck, defendant Scolnick personally profited from the sale of Merck stock at artificially-inflated prices during the Class Period. On October 25, 2000, defendant Scolnick exercised options to purchase 381,200 shares of Merck common stock. The exercise prices of the options were between $16.25 and $21.2805, and Scolnick's cost to exercise all 381,200 options was $7,601,225.10. Scolnick then sold in the open market all 381,200 of the shares resulting from the exercises of those options at the market price of $85.00, for proceeds of $32,402,000.00 and profits of ***$24,800,774.90:***

Date	No. Shares Sold	Price per Share	Sale Proceeds	Exercise Price	Cost of Option Exercise	Profit	% Total Shares, Options
10/25/00	600	$85.00	$51,000	$21.2085	$12,725.10	$38,274.90	58.13%
10/25/00	600	$85.00	$51,000	$16.25	$9,750.00	$41,250.00	
10/25/00	180,000	$85.00	$15,300,000	$18.5625	$3,341,250.00	$11,958,750.00	
10/25/00	200,000	$85.00	$17,000,000	$21.1875	$4,237,500.00	$12,762,500.00	
Total	**381,200**		**$32,402,000**		**$7,601,225.10**	**$24,800,774.90**	

282. When defendant Scolnick stepped-down from the Company on January 1, 2003 (three years and 226 days into the Class Period), he was no longer subject to public reporting requirements concerning the sale of Merck stock. Without the benefit of further discovery, Plaintiffs are unable to ascertain whether defendant Scolnick sold any additional shares of Merck common stock during the Class Period.

[26] As defendant Reicin was not required to file information with the SEC concerning her transactions in Merck securities during the Class Period, without the benefit of further discovery, Plaintiffs are unable to determine whether defendant Reicin, while in possession of material adverse information regarding Merck, profited from the sale of Merck securities at artificially inflated prices.

283. Defendant Scolnick's October 25, 2000 insider sale of 381,200 shares of Merck common stock was unusual in scope because: (i) the approximately $24.8 million in profits he made on this transaction is staggering and represented approximately ***31.4 times*** Scolnick's base salary for 2000 (*i.e.*, $790,000); and (ii) the large number of shares sold by Scolnick represented 58.13% of his combined personal holdings in Merck common stock and exercisable, "in the money" Merck stock options at the time, and represented 100% of his holdings in exercisable "in the money" Merck stock options at the time.

284. Defendant Scolnick's October 25, 2000 sale of 381,200 shares of Merck common stock was also unusual in scope and timing because: (i) during the Class Period, Scolnick acquired ***zero*** shares of Merck common stock through acquisitions that were not related to stock option exercises; (ii) in the three years and 226 days preceding the Class Period, Scolnick exercised Merck options and sold Merck common stock on two occasions, in the amounts of 108,000 shares (on June 13, 1997) and 220,000 shares (on February 17 and 19, 1999), meaning that his October 25, 2000 sale of Merck stock was approximately ***3.5 times*** and ***1.73 times*** greater, respectively, than each of these prior dispositions of Merck stock; and (iii) Scolnick's approximately $24.8 million in profit he made on his October 25, 2000 transaction was ***1.6 times*** greater than the profits he earned on these prior June 1997 and February 1999 stock sales ***combined***. With such totals in the millions of dollars, this magnitude of difference is significant.

XI. LOSS CAUSATION

285. During the Class Period, as detailed herein, Merck and the Officer Defendants engaged in a course of conduct that artificially inflated the price of Merck securities throughout the Class Period. Merck and the Officer Defendants' unlawful conduct directly caused the losses incurred by Plaintiffs and the other members of the Class. The materially false and misleading statements set forth above were widely disseminated to the securities markets, investment

analysts and the investing public. As a result, Plaintiffs and the other members of the Class purchased Merck securities at artificially-inflated prices and were damaged when the artificial inflation gradually dissipated as a result of partial-corrective disclosures entering the market that revealed Merck's and the Officer Defendants' actual beliefs concerning VIOXX's prothrombotic characteristics, and the market's understanding of the impact of the true facts on VIOXX-related sales and VIOXX-related liabilities.

286. By making contemporaneous misstatements in connection with certain partial disclosures of October 2003 and September 30, 2004 as alleged herein, Merck and the Officer Defendants mitigated the impact of those corrective disclosures and prevented the full truth about VIOXX's safety profile and commercial prospects and liability risk, including Merck's and the Officer Defendants' true beliefs concerning the same from being revealed at once. When the true facts became known and/or the materialization of the risks that had been fraudulently concealed by Merck and the Officer Defendants occurred as alleged herein, the price of Merck securities declined significantly as artificial inflation was removed from the market price of these securities, causing substantial damage to Plaintiffs and members of the Class. Discovery and expert analysis may reveal further partial disclosures of corrective information.

287. Between October 22 and October 30, 2003, there was an accumulation of information that partially disclosed the truth concerning the risks that had been misrepresented or fraudulently concealed by Merck and the Officer Defendants concerning VIOXX's actual safety profile and commercial prospects. As set forth above (¶ 173), on October 22, 2003 *Reuters* reported that VIOXX's sales had declined in the third quarter of 2003 due to data "suggesting [VIOXX] might slightly raise the risk of heart attacks, and the growing perception that VIOXX did not have any greater efficacy than traditional NSAIDS." In addition, Credit Suisse First

Boston issued an analyst report on October 22, 2003 informing investors that "Upcoming ACR [American College of Rheumatology] Data could Put Incremental Pressure on Franchise," *i.e.*, that the formal presentation of the aforementioned data from the Merck sponsored Brigham Study, which showed an increased risk of heart attack in patients taking VIOXX compared to patients taking Celebrex or placebo, could result in lowered VIOXX sales. In response to news of the declines in VIOXX sales as a result of the Brigham Study, Merck shares fell almost 7%, or more than $3 per share, to close at $45.72 per share on October 22, 2003. Shortly thereafter, on October 30, 2003, *The Wall Street Journal* published an article concerning the adverse findings observed in the Brigham Study, causing Merck stock to fall to $43.94, reflecting a further 2.2% decline in the price of Merck stock. Nevertheless, due to Merck's and the Officer Defendants' vigorous efforts to discredit the Brigham Study, and their subsequent public statements reassuring investors of VIOXX's purported safety and blockbuster commercial viability, the price of Merck stock remained artificially high, and the fraud continued.

288. Then, on September 30, 2004, Merck shocked investors by announcing the immediate worldwide withdrawal of VIOXX because of "an increased risk of confirmed cardiovascular events" connected to VIOXX. As discussed in ¶¶ 180-181, only weeks earlier, Merck had reiterated its purported good faith belief in the naproxen hypothesis (and VIOXX's commercial prospects) by reaffirming the cardiovascular safety of VIOXX. In response to this second partial disclosure, the Company's stock price dropped from a closing price of $45.07 on September 29, 2004 to close at $33 per share on September 30, 2004, a decline of 27% on exceptionally heavy volume of 145,048,600 shares (which was more than 426% greater than the next highest reported trading volume since January 1990 -- 34,024,200 shares on November 21, 2003 -- and 27 times its normal volume). As discussed in ¶ 184, following the September 30

announcement, securities analysts also expressed their shock and concern at VIOXX's sudden withdrawal.

XII. INAPPLICABILITY OF THE STATUTORY SAFE HARBOR

289. The statutory safe harbor applicable to forward-looking statements under certain circumstances does not apply to any of the false and misleading statements pled in this Complaint. None of the misstatements and omissions complained of herein was a forward-looking statement, nor were any of the statements identified as forward-looking when made. Rather, the false or misleading statements and omissions complained of in this Complaint concerned misstatements and/or omissions of historical and/or current facts and conditions existing at the time the statements were made.

290. Alternatively, to the extent that any of the false or misleading statements alleged herein can be construed as forward-looking statements, they were not accompanied by any meaningful cautionary language identifying important facts that could cause actual results to differ materially from those in the purportedly forward-looking statements. Furthermore, to the extent the statutory safe harbor would otherwise apply to any statement found by the Court to be forward-looking pleaded herein, the Officer Defendants are liable for those false or misleading statements because at the time those statements were made, the speaker(s) knew the statement was false or misleading, or the statement was authorized and/or approved by an executive officer of Merck who knew that the statement was materially false or misleading when made.

XIII. PRESUMPTION OF RELIANCE

291. Plaintiffs are entitled to a presumption of reliance under *Affiliated Ute Citizens of Utah v. U.S.*, 406 U.S. 128 (1972), because the claims asserted herein against Defendants are predicated in part upon material omissions of fact that Defendants had a duty to disclose.

292. In the alternative, Plaintiffs are entitled to a presumption of reliance on Defendants' material misrepresentations and omissions pursuant to the fraud-on-the-market doctrine because, at all relevant times, the market for Merck securities was open, efficient, and well-developed for the following reasons, among others:

i. The market for Merck securities was, at all relevant times, an efficient market that promptly digested current information with respect to the Company from all reliable, publicly-available sources and reflected such information in the price of Merck securities;

ii. Merck common and preferred stock met the requirements for listing and were listed and actively traded on the NYSE, a highly efficient market for securities;

iii. The Company was consistently followed, before and throughout the Class Period, by the media, which issued over 7,000 news stories regarding Merck during the Class Period. Merck was followed by numerous securities analysts employed by firms including Goldman, Sachs & Co., JP Morgan Securities Inc., Merrill Lynch, and Morgan Stanley, among others, who wrote reports about the Company and the value of its securities that were publicly available and entered the public marketplace. Indeed, there was extensive securities analyst coverage of Merck, with over 1,500 analyst reports published during the Class Period;

iv. The price of Merck securities reacted promptly to the dissemination of new information regarding the Company, as set forth above. Merck securities were actively traded throughout the Class Period, with substantial trading volume and average weekly turnover and high institutional investor participation. The average daily trading volume for Merck common stock during the Class Period was 5.5 million shares and the average weekly turnover was 1.2%;

v. Merck regularly communicated with public investors through established market communication mechanisms, including through regular press releases, which were carried by national and international news wires, and through other wide ranging public disclosures, such as communications and conferences with investors, the financial press and other similar reporting services;

vi. As a public company, Merck filed period public reports with the SEC;

vii. Merck met the SEC's requirements to register debt and equity securities filed on Form S-3; and

viii. Merck's securities were rated by rating agencies such as Moody's, Standard & Poor's, and Fitch Ratings.

293. As a result of the foregoing, the market for Merck securities promptly digested current information regarding Merck from all reliable, publicly available sources and reflected such information in the price of Merck's securities. Under these circumstances, purchasers of Merck securities during the Class Period suffered injury through their purchase of Merck securities at artificially-inflated prices and a presumption of reliance applies.

294. Accordingly, Lead Plaintiffs and the other members of the Class did rely and are entitled to have relied upon the integrity of the market price for Merck securities and to a presumption of reliance on Defendants' materially false and misleading statements and omissions during the Class Period.

XIV. CLAIMS FOR RELIEF

COUNT ONE
Violation of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against Merck and the Officer Defendants

295. Lead Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

296. During the Class Period, Defendants Merck and the Officer Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public regarding Merck's business, operations, management and the intrinsic value of Merck securities; (ii) enable Merck and the Officer Defendants to artificially inflate the price of Merck securities; (iii) enable Defendant Scolnick to

sell over $32.4 million of his privately-held Merck shares during the Class Period and while in possession of material adverse non-public information about the Company; and (iv) cause Lead Plaintiffs and other members of the Class to purchase Merck securities at artificially-inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Merck and the Officer Defendants jointly and individually (and each of them) took the actions set forth herein.

297. Merck and the Officer Defendants (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (c) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Merck's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. Merck and the Officer Defendants are sued as primary participants in the wrongful and illegal conduct charged herein.

298. Merck and the Officer Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the business, operations and future prospects of Merck as specified herein.

299. These Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Merck's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and omitting to state material facts necessary in order to make the statements made about Merck and its business operations and future prospects in the light of the circumstances under which they were made, not

misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of Merck securities during the Class Period.

300. Defendant Merck is liable for all materially false and misleading statements made during the Class Period, as alleged above.

301. Merck is further liable for the materially false and misleading statements made by Merck officers in press releases and during conference calls and at conferences with investors and analysts, as alleged above, as the makers of such statements and under the principle of respondeat superior.

302. The Officer Defendants, as top executive officers of the Company, are liable as direct participants in the wrongs complained of herein. Through their positions of control and authority as officers of the Company, each of these Defendants was able to and did control the content of the public statements disseminated by Merck. These Defendants had direct involvement in the daily business of the Company and participated in the preparation and dissemination of Merck's materially false and misleading statements as set forth above.

303. In addition, Defendants Scolnick and Reicin are liable for, among other material omissions and false and misleading statements, the false and misleading statements they made and/or signed.

304. The allegations above establish a strong inference that Merck and the Officer Defendants acted with scienter throughout the Class Period in that they had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts. Such Defendants' material misrepresentations and/or omissions were done knowingly or with

recklessness for the purpose and effect of concealing Merck's operating condition and future business prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Merck and the Officer Defendants' material misstatements and omissions throughout the Class Period, if they did not have actual knowledge of the misrepresentations and omissions alleged, Merck and the Officer Defendants were reckless in failing to obtain such knowledge by recklessly refraining from taking those steps necessary to discover whether those statements were false or misleading.

305. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of Merck securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of Merck's publicly-traded securities were artificially inflated, and relying directly or indirectly on the materially false and misleading statements made by Merck and the Officer Defendants, or upon the integrity of the market in which the securities trade, and/or on the absence of material adverse information that was known to or recklessly disregarded by Merck and the Officer Defendants but not disclosed in public statements by them during the Class Period, Lead Plaintiffs and the other members of the Class purchased or acquired Merck securities during the Class Period at artificially high prices and were damaged thereby.

306. At the time of said material misrepresentations and omissions, Lead Plaintiffs and other members of the Class were ignorant of their falsity, and Merck and the Officer Defendants' material omissions. Had Lead Plaintiffs and the other members of the Class and the marketplace known the truth, they would not have purchased or otherwise acquired their Merck securities, or, if they had purchased or acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

307. By virtue of the foregoing, Merck and the Officer Defendants have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

308. As a direct and proximate result of their wrongful conduct, Lead Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases or acquisitions and sales of the Company's securities during the Class Period.

COUNT TWO
Violation of Section 20(a) of the Exchange Act Against
The Officer Defendants

309. Lead Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

310. The Officer Defendants acted as controlling persons of Merck within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, and their ownership and contractual rights, participation in and/or awareness of the Company's operations and/or intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, the Officer Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Lead Plaintiffs contend are materially false and misleading. The Officer Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by Lead Plaintiffs to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

311. In particular, each of these Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to

control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

312. As set forth above, each of the Officer Defendants violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons, each of the Officer Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of the Officer Defendants' wrongful conduct, Lead Plaintiffs and the other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

COUNT THREE
Violations of Section 10(b) and 20A of the Exchange Act
And Rule 10b-5 Promulgated Thereunder by Defendant Scolnick for Insider Trading

313. Lead Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

314. This claim is asserted pursuant to Section 20A of the Exchange Act against defendant Scolnick by Mississippi PERS (the "20A Plaintiff"), on behalf of itself and other Class members who purchased shares of Merck common stock contemporaneously with the sale of Merck common stock by defendant Scolnick while he was in possession of material, non-public information concerning VIOXX as alleged herein.

315. Defendant Scolnick violated Exchange Act Section 10(b), Rule 10b-5 and Section 20(a) for the reasons stated in Counts One and Two above. Additionally, defendant Scolnick further violated Exchange Act Section 10(b) and Rule 10b-5 by selling shares of Merck common stock while in possession of material, nonpublic adverse information concerning VIOXX's cardiovascular risks, which information he had a duty to disclose, and which he failed to disclose

in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, as more fully alleged herein.

316. Contemporaneously with defendant Scolnick's insider sales of Merck common stock on October 25, 2000, the 20A Plaintiff purchased shares of Merck common stock on a national securities exchange while defendant Scolnick was in possession of material, nonpublic information concerning VIOXX's cardiovascular risks.

317. Other Class members also purchased shares of Merck common stock contemporaneously with defendant Scolnick's insider sales of Merck common stock, including on October 25, 2000.

318. The 20A Plaintiff and other members of the Class have been damaged as a result of the violations of the Exchange Act alleged herein.

319. By reason of his violation of the Exchange Act alleged herein, defendant Scolnick is liable to the 20A Plaintiff and other members of the Class who purchased shares of Merck common stock contemporaneously with defendant Scolnick's sales of Merck common stock during the Class Period.

320. The 20A Plaintiff and the other members of the Class who purchased contemporaneously with defendant Scolnick's Merck securities sales seek disgorgement by the defendant Scolnick of profits gained (or losses avoided) from defendant Scolnick's transactions in Merck common stock contemporaneous with the 20A Plaintiff and other members of the Class.

321. This action was brought within five years after the date of the last transaction that is the subject of defendant Scolnick's violation of Section 20A, and, with respect to the underlying violations of Section 10(b) of the Exchange Act alleged in this Count and in Count

One above, was brought within five years after the date of the last transaction that violated section 20A of the Exchange Act by defendant Scolnick.

XV. PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiffs pray for relief and judgment, as follows:

A. Further determining that this action is a proper class action and further certifying Lead Plaintiffs as class representatives under Rule 23 of the Federal Rules of Civil Procedure with the Class Period as defined herein;

B. Awarding compensatory damages in favor of Plaintiffs and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Ordering the disgorgement by defendant Scolnick of all profits gained and losses avoided to those Class members who purchased Merck common stock contemporaneously with the sales by defendant Scolnick of Merck common stock;

D. Awarding Plaintiffs and the other members of the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

E. Such other and further relief as the Court may deem just and proper.

XVI. JURY TRIAL DEMANDED

Lead Plaintiffs hereby demand a trial by jury of all issues so triable.

Dated: June 14, 2013

/s/ James E. Cecchi
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